Remeasurement confirmed the out of specification results [redacted]. No manufacturing investigation was conducted. A repeat test using a second set of blend samples resulted in an RSD of [redacted]. The batch was completed and released on 4/7/07.

Oxycodone Tablets, 15mg, lot # 70164A failed to meet specifications for blend uniformity on 3/3/07 as shown in the laboratory investigation [redacted] (Exh. 4d1). The specifications for blend uniformity at that time were [redacted] (the specifications did not state whether the [redacted] limits were for individual tablets or for the average [redacted]). The blend uniformity testing of lot # 70164A resulted in an out of specification [redacted] (Exh. 4d1 pp. 1, 7). It should also be noted that sample #1 (Sample location: Left Column – Top Left) had a result of [redacted] remeasurement confirmed the OOS result with an [redacted] (and a result of [redacted] (Exh. 4d1 pp. 3, 9) and no manufacturing investigation was initiated. Instead, a repeat test was performed on a second set of blend samples which resulted in an [redacted] (Exh. 4d1 p.4, 10). It should be noted that during the repeat testing [redacted] (Right Column - Top Center) had a result of [redacted]. A planned deviation [redacted] (Exh. 4d2), was issued on 3/8/07 in order to perform additional content uniformity testing on this lot and the results, which met specifications, are included on pages 6-8 of Exh. 4d2. Lot # 70164A1 was completed and was released on 4/7/07 (Exh. 4d3). This lot remains on the market.

Historical data regarding blend uniformity for Oxycodone HCl is attached as Exh. 4d1 p. 12. The RSD for the blend uniformity testing of the [redacted] included in the historical data are as follows: [redacted] No explanation was provided for the lack of manufacturing investigation, prior to retesting of additional blend samples.

Reference: 21 CFR 211.160(b)(2)

Supporting Evidence and Relevance:
Observation 4a: 4a1-4a12
Observation 4b: 4b1-4b5
Observation 4c: 4c1-4c11
Observation 4d: 4d1-4d3

OBSERVATION 5

Laboratory controls do not include the establishment of scientifically sound and appropriate specifications and test procedures designed to assure that components, in-process materials, and drug products conform to appropriate standards of identity, strength, quality and purity.

Specifically,

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a. **Analytical method transfers for each method from the Little Falls, NJ Quality Control Laboratory to the new Totowa, NJ Quality Control Laboratory were not conducted. Only two types of analytical methods, HPLC and GC were used to support the analytical transfer of approximately [redacted] in-process, finished product and stability methods. There were no analytical method transfers for such techniques as dissolution, atomic absorption, loss on drying, and blend testing.**

The initial purpose of the inspection was to assess the Riverview Drive, Totowa, NJ facility for cGMP purposes to facilitate the transfer of manufacturing and testing operations from the firm's Little Falls, NJ site. Inspection of the Riverview Drive, Totowa, NJ site revealed that the Quality Control Laboratory had already moved and begun testing of raw materials, in-process and finished products and stability samples. A review of the firm's analytical transfer assessment RVF-SER00041 and analytical method transfer protocol, [redacted] (HPLC and GC), dated 8/29/07 and 10/22/07, respectively, (Exh. 5a1, 5a2) revealed equivalency of the laboratories would be evaluated based on [redacted] by HPLC (Exh. 5a3) and 2 products by GC (Exh. 5a4). The rationale for the methods used and products tested was not fully documented and did not indicate how the limited evaluation was representative of the approximately [redacted], finished product and stability methods that were transferred (The number of methods was estimated by [redacted] and provided to us by Ms. Lambridis). A table noted as, "Equipment Subject to Transfer to Actavis Riverview" (Exh. 5a1 pp. 8-9) described laboratory techniques, equipment, qualification status, and whether equivalency was required. Such techniques as dissolution, atomic absorption, loss on drying and blend testing which are commonly used in the laboratory were not evaluated for equivalency. Ms. Lambridis stated that the original philosophy for the transfer was that because of the same FEI number was assigned to the new facility (Riverview Drive), the transfer activities of same analysts, methods, and equipment were not considered as a significant change. We discussed the need to re-evaluate methods and equipment when changing facilities, despite the distance between the two sites. [redacted] stated that for testing such as dissolution, the analytical technique required for the sample is HPLC or UV. Representative products were selected to try to encompass various laboratory techniques. We stated that a matrix approach to the transfer may have been acceptable; however it would require broader coverage of the numerous laboratory techniques, methods, and equipment. We stated that such approaches are frequently discussed in advance with the District office. There was no documented explanation for the move or the initiation of testing at the new Quality Control Laboratory at Riverview Drive, Totowa, prior to a qualifying cGMP inspection. At the exit meeting we stated that we did not expect a formal transfer of each analytical method; however we did expect a scientifically sound approach to the complete transfer of the Quality Control Laboratory for the testing, release and stability of all products. Mr. Wessman and Mr. Olafsson stated that they understood the concern. Ms. Lambridis clarified that it would be acceptable to supplement the completed transfer activities and documentation to assure suitability of the transfer. We stated that the laboratory including the transfer activities would be evaluated on the follow-up inspection.

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b. **There is no analytical evaluation of impurities on stability for approximately 48 prescription drug products such as Oxycodone HCl Tablets, 5mg, Phenazopyridine HCl Tablets, 200mg, Methenamine Mandelate Tablets, USP 1g, and Prenatal Plus with 27mg Iron Tablets to assure the strength, quality, and purity of the products throughout expiry.**

During the evaluation of Chlordiazepoxide and Clidinium Bromide Tablets 5mg/2.5mg, for an out of specification assay result on stability, (see FDA 483 observation 3h), a large unkown chromatographic peak was observed between the two active peaks (Exh. 3h3 p. 36, 3h12). Upon request of the specification for impurities for the product, it was determined that there was no stability specification for impurities. I, Investigator McCaffery requested a comprehensive list from Ms. Lambridis to include any products that did not have impurity testing on stability. [redacted] prescription pharmaceutical products which did not have impurity testing was provided (Exh. 3h11). Examples of products without impurity testing include: Oxycodone HCl Tablets, 5mg, Phenazopyridine HCl Tablets, 200mg , Methenamine Mandelate Tablets, USP 1g, and Prenatal Plus with 27mg Iron Tablets (Exh. 5b1). We asked Ms. Lambridis what assurance the firm has of the strength, quality, and purity of the products throughout expiry in the absence of impurity testing. We discussed the large degradant of chlordiazepoxide which was only observed because of an out of specification (low) assay. Impurity peaks that did not result from degradation or degradants in smaller quantities were not being evaluated to assure the safety and efficacy of the product. Ms. Lambridis acknowledged the potential risk of the products and provided a commitment to the New Jersey District Coordinator on 5/19/08 to voluntarily recall all 48 products from the market.

c. **A stability out-of-specification result for the Betaxolol Hydroxyethyl impurity [redacted] was observed during related substance testing of Betaxolol Tablets 10mg USP, lot# 60215A1 at the [redacted] time point. The impurity co-eluted with the solvent/placebo peak. Although it was determined that a new analytical method was required to adequately evaluate the product, the firm continued testing and releasing product to the marketplace. The Quality Assurance investigation was not completed at the time of inspection and approximately [redacted] lots remained on the market.**

Laboratory [redacted] documented a stability out-of-specification result for the Betaxolol Hydroxyethyl impurity [redacted] that was observed during related substance testing of Betaxolol Tablets 10mg USP, lot# 60215A1 at the [redacted] (Exh. 5c1). The laboratory notebook (Exh. 5c2) and chromatograms (initial) (Exh. 5c3), remeasurement (Exh. 5c4), and repeat testing (Exh. 5c5) were provided. The following table summarizes the results of the impurity testing for the known impurity, Betaxolol Hydroxyethyl.

Betaxolol Tablets 10mg USP, lot# 60215A1	Betaxolol Hydroxyethyl Impurity % [redacted]
Initial	[redacted]
Remeasurement (original vial)	[redacted]
Remeasurement (original stock)	[redacted]

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Establishment Inspection Report	FEI:	2244683
Actavis Totowa LLC	EI Start:	03/18/2008
Totowa, NJ 07512	EI End:	05/20/2008

Repeat Test	[redacted]

A draft addendum t[redacted] includes the following conclusion, "Based on the investigation, no laboratory related assignable cause was identified. The re-measurement results supported the initial OOS results. The repeat test for Betaxolol Hydroxyethyl was [redacted] which met the specification, however, the repeat test results somewhat confirmed the initial results. The average result of initial and repeat test was reported for the subject batch. The subject batch has an expiration date of March, 2008. A full scale investigation [redacted] was initiated as [redacted] QA will determine the disposition of the subject batch." (Exh. 5c6) A one page draft, [redacted] (Exh. 5c7), only listed the out of specification data and did not document any investigative work.

Review of the chromatograms revealed that an in-house standard was used for the product. The standard chromatograms show incomplete separation between the placebo and the Betaxolol Hydroxyethyl impurity. Additionally, the active chromatographic peak for Betaxolol appears to co-elute with [redacted] (Exh. 5c3 p. 18). The sample chromatograms also exhibited co-elution of the placebo peak with Betaxolol Hydroxyethyl and co-elution of [redacted] with the active Betaxolol peak (Exh. 5c3 pp.29-31). We discussed the inability of the chromatography to adequately resolve chromatographic peaks. [redacted] stated that they were aware of the issues with the method. Mr. Talbot explained that an [redacted] was used historically for assay and impurity testing. It was no longer commercially available and an equivalency study was conducted using [redacted] to try to find a replacement (Exh. 5c8). An Atlantis column was selected as the [redacted] with the existing method, [redacted] (Exh. 5c9) based on the study. We discussed the issues with the current method and column and stated that separation of the peaks was inadequate to quantify the active ingredient and the known and unknown impurities. We questioned whether the analytical method was stability indicating based on the poor separation and split peaks.

[redacted] and Mr. Talbot explained that a new analytical method would be required to adequately resolve the placebo from the known impurity peak and to allow better separation for the active peak. A protocol was written and a new method for related substances was developed 10/07 following a method comparison, according to Mr. Talbot (Exh. 5c10). A new analytical method for related substances was filed as a [redacted] n 4/21/08 during the inspection (Exh. 5c11). The method changed from an isocratic to a gradient method with a modified mobile phase, and a change in wavelength from [redacted]. We noted our continued concerns regarding the inability of the assay method to adequately separate [redacted] from the active peak. Although the out of specification stability results were obtained on 3/20/08, no evaluation of the approximately [redacted] batches on the market was conducted (Exh. 5c12). Mr. Talbot and Ms. Lambridis stated that the product was going to remain on the market despite the stability out of specification results, because they felt the issue was method related. Mr. Talbot stated that the product, if tested with the newly filed method, meets specifications. We stated that the currently filed and approved method and specifications should be the basis for product quality decisions until the new method is approved. They planned to test stability batches for related substances with both the current and modified methods (Exh. 5c13).

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d. **There is no assurance that all prescription vitamin products will maintain their labeled potency throughout expiry. Testing of all labeled ingredients on stability is not conducted. For example pediatric prescription multi-vitamins, Mutli Vita-Bets with 0.25mg, 0.5mg, and 1.0mg Fluoride and Iron Chewable Tablets and pre-natal prescription vitamins, Prenatal Plus with 27mg Iron Tablets are not analyzed for Iron on stability.**

(Note: An error was noted following the issuance of the FDA 483. The 0.25mg Multi Vita-Bets formulation was incorrectly cited. The strengths which lack testing for iron include 0.5mg and 1.0mg Multi Vita-Bets with Fluoride and Iron Chewable Tablets.)

In discussions with Apurva Patel, Managing Director regarding the prescription products currently manufactured without an application, he explained that in the past, they manufactured prescription vitamins and considered them "nutritionals". He stated that they did not view the products in the same way as other filed products. Following discussions with FDA and industry wide Warning Letters for several "DESI" products, they had begun to increase testing and evaluated the products more rigorously. We discussed the testing of the prescription vitamin products. Mr. Patel stated that they test all ingredients on release, but only a portion of the ingredients on stability. I, Investigator McCaffery requested a list of all ingredients tested for release versus stability. Mr. Patel provided the list of the ingredients tested on release and stability for the prescription vitamin products (**Exh. 5d1**).

The list included [redacted]s. It was observed that the stability testing requirements were fewer than the testing on release. For example, pediatric prescription multi-vitamins, Multi Vita-Bets with 0.5mg, and 1.0mg Fluoride and Iron Chewable Tablets were tested for iron on release, but the iron content was not evaluated on stability (**Exh. 5d1 pp. 5-6**). A pre-natal prescription vitamin, Prenatal Plus with 27mg Iron Tablets were also tested on release for iron but not on stability (**Exh. 5d1 p. 9**). It was noted later in the inspection that approximately [redacted] prescription products [redacted] as well as Prenatal Plus with 27mg Iron Tablets have no impurity testing on stability (**Exh. 3h11**). I, Investigator McCaffery, discussed the issues with Mr. Patel and later with Ms. Lambridis. I noted the potential risk of not testing for the ingredients to assure that the product meets it's label claim throughout expiry and the potential health risk associated with degradants and unknown impurities. Mr. Patel and Ms. Lambridis understood the concerns. We were notified by Ms. Lambridis during the inspection that the firm intended to discontinue manufacturing the prescription vitamins. New Jersey District Recall Coordinator was notified on 5/19/08 of the firm's intention to voluntarily [redacted] without impurity testing on stability including all of the [redacted]escription vitamins for which all ingredients were not analyzed on stability.

e. **Out of specification or suspect test results for low assay were reported for Amantadine HCl Capsules, 100mg in OOSN 06-015, dated 11/16/06, STR 07-065, dated 7/3/07, OOSN 07-168, dated 12/4/07 and OOSN 07-183, dated 12/29/07. OOSN 07-168 resulted in a confirmed 18-month out of specification stability result for assay; however the other investigations attributed the low assay results to**

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"extraction issues" with the GC method and manufacturing investigations were not conducted. Although the need for method remediation has been documented for the GC extraction method for assay of Amantadine HCl Capsules, 100mg since 11/16/06, corrective actions have not been implemented. QA Investigation 08-003 for the out of specification stability result obtained 12/4/07 remained in draft at the time of inspection.

The following investigations into out of specification results and suspect test results attributed the low assay results to the analytical method [redacted] (Exh. 3d 11), a GC extraction method. However a confirmed stability out of specification result for Amantadine Hydrochloride Capsules, 100mg at the [redacted] stability timepoint did not include a manufacturing investigation to rule out other potential sources for the low assay results. Additionally at the time of inspection, the analytical method was not remediated despite the known extraction issues documented since 11/16/06.

Laboratory investigation [redacted] documents an initial out of specification low assay result for Amantadine HCl Capsules, 100mg, lot# 60325A1 at [redacted] stability timepoint (Exh. 5e1). Assay results of [redacted] were obtained 11/16/06. Remeasurement results were [redacted] Repeat test results for assay performed on freshly prepared sample solutions by a different analyst using the same instrument resulted in [redacted] The conclusion of the laboratory investigation states, "The incomplete extraction of the active ingredient from the solution during the sample preparation was identified as an assignable cause for the OOS result." (Exh. 5e1 p. 10).

Laboratory investigation [redacted] documents an initial suspect test result for low assay for finished product release testing of Amantadine HCl Capsules, 100mg, lot# 70483A. The assay results obtained 7/3/07 were [redacted] (Exh. 5e2). The reshaken stock solution was filtered and then working solutions were prepared and injected. The assay results were [redacted]. Repeat testing by a different analyst using the same instrument and column with new standard and sample preparations resulted in assay values of [redacted] The root cause of the failure was identified as, "an extraction error during sample preparation." (Exh. 5e2 p. 11)

Draft laboratory [redacted] documents the out of specification assay results which were obtained on 12/4/07 for Amantadine Hydrochloride Capsules, USP, 100mg, lot# 60324A1, at the [redacted] (Exh. 3d1). A draft addendum to [redacted] (undated, unsigned) was also provided (Exh. 3d2.) The draft addendum states that the, "root cause seems to be method related". (Exh. 3d2 p. 3) The assay results for remeasurement were [redacted] (reextracted solution). Repeat testing conducted by a second analyst resulted in assay [redacted] (Exh. 3d2 p. 3).

Laboratory investigation [redacted] documents initial out of specification low assay results for

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the [redacted] (Exh. 5e3). Assay results [redacted] obtained 12/29/07. A draft addendum to [redacted] (Exh. 5e4 p. 2) included remeasurement results of [redacted] Repeat test results for assay performed in quadruplicate by a second analyst resulted in [redacted] (Exh. 5e4 p. 2). The conclusion of the laboratory investigation states, "Based on the investigation, no laboratory related assignable cause was identified. The repeat test result met the specification. The average of repeat test result will be reported for the subjected batch." The draft addendum was not signed or dated and Mr. Talbot and Mr. Roychowdhury confirmed that all the results we discussed were considered "method related". A timeframe extension for [redacted] indicates, "The investigation was on hold due to the similar issue in the other investigation. The root cause for the inconsistent assay results seems to be method related. The current GC method involves internal standard and multi-step extraction. The method remediation is underway...," dated 3/19/08 (Exh. 5e5). A list of current method remediation projects was provided as Exh. 5e6). We discussed the failure to respond to the method issues and the need to rule out other potential sources of the low assay results. A commitment to voluntarily recall the approximately [redacted] on the market was provided to New Jersey District Recall Coordinator on 4/9/08 (Att.)

Reference: 21 CFR 211.160(b)

Supporting Evidence and Relevance:
Observation 5a: 5a1-5a4
Observation 5b: 3h3, 3h11, 5b1
Observation 5c: 5c1-5c13
Observation 5d: 5d1, 3h11
Observation 5e: 3d11, 5e1-5e6, 3d1, 3d2, Att

OBSERVATION 6

Investigations of an unexplained discrepancy and a failure of a batch or any of its components to meet any of its specifications did not extend to other batches of the same drug product and other drug products that may have been associated with the specific failure or discrepancy.

We discussed the failure of Quality Assurance to document and complete investigations at the time of occurrence with Ms. Lambridis. A list of Quality Assurance Investigations from 9/07 to the present by product was requested (Exh. 6). The list revealed that the investigations into out of specification results (as documented in FDA 483 observations 2, 3, and 4), remained open. [redacted], was introduced during the inspection. She joined the company 1/08 and will oversee QA investigations, CAPAs, and complaints for the New Jersey sites. I, Investigator McCaffery asked Ms. Sherwani how she planned to remediate the backlog of QA investigations in the absence of adequate staffing and systems. She explained that

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she is trying to work closely with Quality Control to understand the laboratory findings and plans to increase her group to respond to the backlog. Ms. Lambridis confirmed that they needed additional resources and were hiring, but were not fully staffed. We discussed the need to address out of specification product in a timely manner. On several occasions during the inspection, Ms. Lambridis stated that she needed time to stop and review the product issues. Due to the lack of documentation and completions of the QA investigations, the investigative information was not compiled reviewed or approved. In some cases, Ms. Lambridis had not been made aware of the significant quality issues by local quality personnel.

Specifically,

a. Although [redacted] dated 1/25/08, for double thick Digoxin Tablets 0.125mg, lot# 70924A1, did not establish a root cause for the defective tablets, the investigation was not expanded to evaluate all finished product lots or strengths of Digoxin Tablets. At the time of inspection there were approximately [redacted] lots of Digoxin Tablets 0.125mg and [redacted] lots of Digoxin Tablets 0.250mg on the market within expiry.

A Quality Assurance investigation, [redacted] dated 1/25/08, for Digoxin "double thick" tablets, lot# 70924A1 failed to establish a root cause for the defective tablets (Exh. 2a1) as documented in FDA 483 observation 2a. The product was visually inspected to remove the "double thick" tablets and was subsequently released to the market (Exh. 2a3 p.6). The product continued to be manufactured with no assurance that other batches had been or would be impacted by the issue. There was no health hazard evaluation conducted to determine the potential patient impact upon taking a "double thick" Digoxin Tablet. There were [redacted] of Digoxin Tablets, 0.125mg and [redacted] lots of Digoxin Tablets, 0.250mg which are manufactured on the same equipment, with the same operators and raw material supply. The QA investigation was signed by the Director of Quality Assurance, who noted in the impact analysis, "The deviation is considered an isolated incident; therefore no other batches are impacted." (Exh. 2a1 p. 2) Ms. Lambridis notified us on 4/17/08 that the firm was voluntarily recalling lot# 70924A2 (repack of lot# 70924A1 following visual inspection). We discussed the failure to evaluate other batches due to the lack of root cause in the investigation and the discrepancies between the investigational theories among firm personnel. We notified the District of our findings during the inspection and District Management contacted CDER Office of Compliance during the inspection due to the potential risk of "double thick" tablets. Robert Wessman, CEO was contacted by New Jersey District on 4/24/08

b. Although a tablet capping issue was identified for Oxycodone Tablets 5mg, lot# 70976A on 12/14/07 and was attributed to damaged punches and dies in [redacted] the investigation did not evaluate the impact on other finished product lots or strengths. Subsequently, four additional lots of Oxycodone HCl Tablets exhibited tablet capping, (30mg) lot# 80095A1, 80096A1, 80174A1; (15mg) 80165A1. [redacted] for capping of Oxycodone HCl Tablets conclude that no other batches are impacted. Manufacturing of all strengths of Oxycodone Tablets

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continued despite the capping issues.

Quality Assurance investigation [redacted] documented capped tablets observed during the packaging of Oxycodone Tablets 5mg, lot# 70976A on 12/14/07 (Exh. 6b1). The investigation stated that capped tablets were observed in finished product [redacted] Upon further inspection, operators also found capped tablets in [redacted] The product was compressed on [redacted] tablet presses [redacted] During the compression of a subsequent batch, #71045A, capping was noticed during the start of compression. A common set of lower punches and dies [redacted] was used. The operator noted small lines in [redacted] that were thought to be consistent with the marks found on some of the capped tablets. The root cause for the capped tablets was determined to be the "damaged lower punches and dies of [redacted] Although the QA investigation evaluated the two batches with noted capping and the batch produced between the two capped batches, no other tooling or other possible causes for the capping were documented. Subsequently, tablet capping was documented in four additional lots of Oxycodone HCl Tablets, (30mg) lot# 80095A1, 80096A1, 80174A1; and (15mg) 80165A1 as documented in QA investigations [redacted] QA investigation [redacted] (Exh. 6b2) includes (30mg) lot#s 80095A1, 80096A1, and (15mg) lot# 80165A1. The capping was found during packaging and was attributed to one of two tablet presses (#81) used for the lots. There was no evaluation of other aspects of manufacturing or formulation. The tablets produced by tablet press #68 were released (Exh. 6b3); however tablets produced on [redacted] were placed on hold by QA to be, "reassessed at a later time." (Exh. 6b4) [redacted] includes an impact analysis which states, "There is no impact on other batches manufactured. The issue was isolated to [redacted] batches." (Exh. 6b2 p. 3).

A third QA investigation, [redacted] regarding Oxycodone HCl Tablets, USP, 30mg lot# 80174A1, documents capped tablets found during the beginning of the packaging operation on 3/6/08. A small number of [redacted] were identified in [redacted] (Exh. 6b5). The impact analysis written by the Director of Quality Assurance notes, "There is no impact on the batch. Based on the results of this investigation, no other batches are impacted."

At the time of inspection, the capped tablet issue was not fully investigated for Oxycodone HCl Tablets, USP and each QA investigation considered the capped tablets isolated events. Other potential sources of the capped tablets were not evaluated. During a walkthrough of the Little Falls, NJ facility on 4/22/08, we observed that Oxycodone HCl Tablets USP, 15mg and 30mg were being manufactured on that day and equipment logbooks revealed that the 5mg Tablets were also recently produced, for example on 4//17/08 in the double cone blender (Exh. 6b6 p. 10)

c. Although an out of specification assay value [redacted] was obtained at the [redacted] stability testing time point for Phentermine HCl Capsules 30 mg, lot# 5436A1 on 7/25/07, QA Investigation 07-066 concludes, "No other batches are impacted by this stability failure." No root cause was identified and the investigation was not expanded to evaluate all finished product lots of Phentermine HCl Capsules. There are currently [redacted] lots of Phentermine HCl Capsules

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30 mg on the market within expiry.

Although lot# 5436A1 is an annual stability batch (Exh. 3b7) which was out of specification for assay at the [redacted] as documented in FDA 483 observation 3b, QA investigation [redacted] indicates, "No other batches are impacted by this stability failure." (Exh. 3b6 p. 5) A second out of specification (high assay) stability result at the [redacted] was obtained for Phentermine Capsules, 30mg, lot# 5704AQ [redacted] on 12/3/07 as documented in [redacted] (Exh. 3b8). No explanation was provided for the failure of the Quality Unit to expand the initial Quality Assurance investigation to determine the root cause.

d. An error was identified in the formula calculation for Vitamin B1 (Thiamin) during the testing of the pediatric prescription vitamin, Multi Vita-Bets with 1.0 mg Fluoride, lot # 70602A1 at the [redacted] stability test point on 11/22/07. It resulted in Thiamin assay values being reported approximately [redacted] higher than the actual assay value for all lots. Although a planned deviation was written 1/17/08 to correct the calculation for 5 different pediatric multi-vitamin prescription formulations containing Vitamin B1 (Thiamin), the QA investigation 08-021 was not initiated until 2/14/08 and only evaluated other lots of Multi Vita-Bets. The investigation failed to evaluate all products which contain Vitamin B1 (Thiamin). In addition, the QA investigation, which remains incomplete, describes the impact of the deviation on batches as "Since these are non-ANDA products, and the assay results would fall below the specification, there is no significant impact as a result of this deviation."

FDA 483 observation 3j documents the calculation error for Thiamin in Multi Vita-Bets with 1.0mg Fluoride, lot# 70602A1 at the [redacted] stability test point on 11/22/07. The recalculation of the initial out of specification result caused the batch to meet specifications; however the investigation did not expand to other lots or products. Although it was determined by inspection that there are [redacted] formulations and [redacted] product formulations containing Thiamin, the initial QA investigation, [redacted] was not initiated until 2/14/08 and only evaluated other lots of Multi Vita-Bets (Exh. 3j14). A planned deviation, dated 1/17/08, (Exh. 3j6), also only evaluated the [redacted] formulations. The QA investigation, which remains incomplete, describes the impact of the deviation on batches as "Since these are non-ANDA products, and the assay results would fall below the specification, there is no significant impact as a result of this deviation." (Exh. 3j14) A list of the other [redacted] products containing Thiamin which were not considered at the time of inspection was provided as Exh. 3j7. No explanation was provided for the delay in evaluating the first [redacted] containing Multi Vita-Bets formulations or the additional [redacted] The QA investigation remained incomplete at the time of inspection. The recalculations revealed that three of the Multi Vita-Bets products were out of specification. On 4/9/08, New Jersey District Recall Coordinator was notified of the recall of all batches of Multi Vita-Bets, with Fluoride 0.25mg, 0.5mg and 1.0mg.

These pediatric prescription vitamins were marketed without an approved application (See the

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"PRESCRIPTION PRODUCTS WITHOUT APPROVED APPLICATIONS" section of this report. We were notified on 4/9/08 that all lots of Multi-vita Bets Tablets, 0.25mg, 0.5mg, and 1.0mg were being voluntarily recalled. On 4/22/08, in a letter from Ms. Lambridis, a commitment to "cease distribution and manufacture of DESI products." **(Exh. 13)** The New Jersey District Recall Coordinator was notified on 5/19/08 that the firm was also voluntarily recalling approximately [redacted] prescriptions products **(Exh. 3h11)** which do not have impurity specifications on stability. The list to be recalled includes a number of the Thaimin containing products such as Prenatal Plus with 27mg Iron Tablets, Vitaplex Tablets, and Vitacon Forte Capsules.

Reference: 21 CFR 211.192.

Supporting Evidence and Relevance:
Observation 6: 6
Observation 6a: 2a1, 2a3
Observation 6b: 6b1-6b6
Observation 6c: 3b6-3b8
Observation 6d: 3j14, 3j6, 3j7, 13, 3h11

OBSERVATION 7

An NDA-Field Alert Report was not submitted within three working days of receipt of information concerning a failure of one or more distributed batches of a drug to meet the specifications established for it in the application.

A list of the NDA Field Alerts filed at the time of inspection was provided as **Exh.** 7. An updated list of all Field Alert Reports received during and after the inspection by New Jersey District is provided as (Att). Ms. Lambridis discussed the firm's historical hesitation to notify FDA of potential product quality issues. She stated that when she joined the company and began to evaluate some of the out of specification stability results, she prompted the filing of the Field Alerts. She stated that since the hiring of Misbah Sherwani, Senior Manager Quality and Investigation, they have been filing reports on time. Ms. Lambridis stated that Field Alerts will be filed within three days of the initial findings as per regulation.

Specifically, field alert reports for the following products with confirmed stability out of specification results were not submitted within three working days of receipt of information:

a. Phentermine HCl Capsules, 30mg [redacted] stability lot# 5436A1 (1000 count), was out of specification for high assay on 7/25/07.

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Phentermine HCl Capsules, 30mg [redacted] stability lot# 5704AQ (100 count), was out of specification for high assay on 11/30/07. The field alert report was filed 4/24/08, during the inspection.

See FDA 483 observation 3b regarding the out of specification assay results on stability for Phentermine HCl Capsules, 30mg ANDA 40-227 (Exh. 21). The results were obtained on 7/25/07 (Exh. 3b1). No NDA Field Alert Report was filed at the time of occurrence. A second out of specification assay result on stability for Phentermine HCl Capsules, 30mg, [redacted] lot# 5704AQ (100 count), was obtained on 11/30/07 (Exh. 3b8). No NDA Field Alert was filed at the time of occurrence. During the inspection, following our discussions about the out of specification stability results, an NDA Field Alert was filed on 4/24/08 (Att).

b. Glyburide (Micronized) Tablets USP 1.5mg, [redacted] stability lot# 60164A1 (100 count) was out of specification for a known impurity, methoxysulphamide, on 10/3/07. The field alert report was filed 11/29/07.

See FDA 483 observation 3g regarding out of specification known impurity results for Glyburide (Micronized) Tablets USP 1.5mg, (ANDA 75-947) (Exh. 21), [redacted] stability lot# 60164A1. The results were obtained on 10/3/07 (Exh. 3g1). The NDA Field Alert Report was not filed until 11/29/07 (Att).

c. Pentazocine and Naloxone Hydrochloride Tablets USP 50mg/0.5mg, [redacted] lot# 70053A2 was out of specification for assay of Naloxone on 1/3/08. The field alert report was filed 2/3/08.

See FDA 483 observation 2b regarding the out of specification (high) assay results for Naloxone in Pentazocine and Naloxone Hydrochloride Tablets USP 50mg/0.5mg, (ANDA 75-735), [redacted] lot# 70053A2. The results were obtained on 1/3/08 (Exh. 2b1). The NDA Field Alert Report was not filed until 2/3/08 (Att).

d. Mirtazapine Orally Disintegrating Tablets, 15mg, [redacted] 25°C/60%RH stability lot# 60794A1 (blister pack) was out of specification for a known degradant, MTZNO, on 1/4/08. The field alert report was filed 4/4/08, during the inspection.
It was noted following the inspection that the laboratory raw data was obtained 1/3/08 instead of 1/4/08. OOSN 08-002,laboratory investigation was initiated on 1/4/08.

See FDA 483 observation 3f regarding the out of specification impurity results for the known degradant, [redacted] in Mirtazapine Orally Disintegrating Tablets, 15mg, (ANDA 76-689), [redacted] lot# 60794A1 (blister pack) was out of specification for a known degradant, [redacted]. The results were obtained on 1/3/08 (Exh. 3f1). The NDA Field Alert Report was not filed until 4/4/08 (Att).

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Establishment Inspection Report	FEI:	2244683
Actavis Totowa LLC	EI Start:	03/18/2008
Totowa, NJ 07512	EI End:	05/20/2008

Reference: 21 CFR 314.81(b)(1)(ii)

Supporting Evidence and Relevance:
Observation 7: 7, Att
Observation 7a: 21, 3b1, 3b8, Att
Observation 7b: 21, 3g1, Att
Observation 7c: 2b1, Att
Observation 7d: 3f1, Att

OBSERVATION 8

Written records are not always made of investigations into unexplained discrepancies and the failure of a batch or any of its components to meet specifications.

Specifically, Quality Assurance investigations are not documented at the time of occurrence and are not completed in a timely manner as required by [redacted] Deviations, dated 11/3/06. For example:

a. **There is no completed Quality Assurance investigation into the formulation and analytical method calculation errors that led to the overage of approximately 9% Naloxone for all batches of Pentazocine and Naloxone Hydrochlorides Tablets, USP, 50mg (base)/0.5mg (base) from 9/8/05 until 3/25/08. The out of specification 9-month assay results for lot# 70053A2 were obtained 1/3/08 and the formulation error began 9/8/05.**

There was no QA investigation documented for the known formulation and analytical method calculation errors that led to the overage of approximately [redacted] for all batches of Pentazocine and Naloxone Hydrochlorides Tablets, USP, 50mg (base)/0.5mg (base) from 9/8/05 until 3/25/08. (See FDA 483 observation 2b.) Although [redacted] laboratory investigation, dated 1/3/08, (Exh. 2b1) documented out of specification [redacted] for lot# 70053A2, there was still no QA investigation at the time of inspection. An interim report to extend the timeframe was approved by QA on 3/20/08, during the inspection (Exh. 8a1). "Root cause has been determined to be an overcharge of Naloxone as the amount presented on the Master Formula Sheet of the MPR has been corrected for moisture. However, the MPR further requires the correction for moisture, resulting in overcharge. A review of all lots manufactured since the effective date of the MPR is currently being conducted and all lots are being calculated correctly to determine scope. MPRs have been corrected." There was no documentation provided for any of the activities referenced in the timeframe extension. We discussed the failure to document the QA activities and to provide information to make decisions on product quality in a timely manner with Ms. Lambridis. She stated that she was surprised by the lack of documentation of the QA work because she was aware of numerous activities that were being

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conducted. During the inspection, we requested documentation to show which Master Production Record revisions included the erroneous calculations. It was determined that MPR 21102, Revisions 5 through 7 (Exhs. 2b14-16) contained the incorrect calculations leading to the overage for all batches manufactured from 9/8/05 until 3/25/08.

A second deviation was noted in that the laboratory practice was to dry the in-house standard for Naloxone HCl Dihydrate, however the method did not correct for drying the standard so the analysis did not reveal the overage. The deviation was noted in a document entitled, "QA Investigation [redacted] Follow Up for Pentazocine/Naloxone Tablets, " (Exh. 2b21), which was a draft to the unwritten QA investigation.

b. **There was no completed Quality Assurance investigation into the two out of specification assay results for Carisoprodol, Aspirin and Codeine Phosphate Tablets, 200/325/16mg, lot# 60484A1, obtained 8/21/07 and 1/16/08, respectively for the [redacted] stability time points. A bilayer manufacturing problem was identified 8/28/07 in [redacted] regarding an out of specification acceptance value for Carisoprodol, [redacted] in Carisoprodol, Aspirin, and Codeine Phosphate Tablets, 200/325/16mg, lot# 70484A. Despite the known bilayer manufacturing problem and stability out of specification results, the Master Production Record was not placed on hold until 2/29/08 and the Master Production Record for another bilayer product, Carisoprodol/Asprin Tablets 200/325mg, was not placed on hold until 4/7/08, during the inspection.**

See FDA 483 observation 3a. Two out of specification assay results on stability for Carisoprodol, Aspirin and Codeine Phosphate Tablets, 200/325/16mg, lot# 60484A1 were obtained 8/21/07 and 1/16/08 (Exh. 3a1) and a bilayer manufacturing problem was identified 8/28/07 in laboratory investigation [redacted] which documented an out of specification acceptance value for Carisoprodol, [redacted] in Carisoprodol, Aspirin, and Codeine Phosphate Tablets, 200/325/16mg, lot# 70484A (Exh. 3a10). Despite the confirmed stability failures, there was no completed QA investigation at the time of inspection.

Although the draft QA investigation [redacted] references, "A root cause for the bi-layer issue considered the point of production when the compressed tablet samples are taken, sighting that the problem likely occurs at the end of the production run when the hopper is almost empty for one of the two layers." The unsigned draft also includes, "A root cause for the subject deviation was determined to be that the batch was impacted by the degradation and hydrolysis of the Aspirin layer to form Salicyllic Acid." (Exh. 3a3 pp. 3-4). An extension for QA investigation [redacted] was approved by QA on 3/19/08, 7 months after the original out of specification stability results, with a target completion date of 4/18/08 stating, "Additonal assessment of impact on marketed lots is necessary to closeout investigation. Determine how many in-date lots are currently on the market." (Exh. 3a4).

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The QA investigation, [redacted] for the acceptance value failure of lot# 70484A was completed and approved 11/9/07 and resulted in the rejection of the batch. The QA investigation states, "Impact of deviation has yet to be determined for this product." (Exh. 3a11 p. 3) Investigations of the more recent stability failures were not initially attributed to the manufacturing issue and no correlation to [redacted] was made. The Master Production Record was not placed on hold until 2/29/08 and the Master Production Record for another bilayer product, Carisoprodol/Aspirin Tablets 200/325mg, was not placed on hold until 4/7/08, during the inspection (Exh. 3a18-3a19). No market action was taken until 4/4/08 when New Jersey District Recall Coordinator was notified that the firm was voluntarily recalling the approximately [redacted] on the market within expiry.

c. **No QA investigation was initiated following the confirmed stability out of specification known impurity, MTZNO at the [redacted] for Mirtazapine Orally Disintegrating Tablets, 15mg, lot# 60794A1 on 1/4/08. [redacted] additional out of specification stability results were obtained for lot#s 70279A1 (9-month), 70420A2 (6-month), and Mirtazapine Orally Disintegrating Tablets, 30mg, lot# 70421A1 on 2/26/08 for the same known impurity. The QA investigation remained in draft during the inspection.**

See FDA 483, observation 3f. Although four out of specification stability results for a known degradant, [redacted] were obtained for Mirtazapine Orally Disintegrating Tablets 15mg, lot# 60794A1 [redacted] on 1/4/08 and lot#s 70279A1 [redacted] 70420A2 [redacted] and 70421A1 [redacted] QA investigation was provided for the during the inspection (Exh. 3f 16). It contained only the out of specification results for lot#s 70279A1 [redacted] 70420A2 [redacted] and 70421A1 [redacted] There were no documented investigative steps to determine the root cause, no discussion of the risk associated with the OOS results and no evaluation of the lots on the market. During the inspection, a new draft, [redacted] was provided which included [redacted] lots which noted that "all in date marketed product will be recalled. New Jersey District Recall Coordinator was notified 4/9/08 of the voluntary recall.

d. **There was no completed Quality Assurance investigation into the [redacted] stability out of specification Folic Acid assay results for Multiret Folic 500 Tablets, lot#s 70607A1 and 70065A1 obtained 1/11/08 and 2/28/08, respectively.**

See FDA 483 observation 3i. Although out of specification low assay results for Folic Acid were obtained during the testing of Multiret Folic 500 Tablets, lot#s 70607A1 [redacted] and 70065A1 [redacted] on 1/11/08 and 2/28/08, respectively, and as documented in [redacted] (Exh. 3i1) and [redacted] (Exh. 3i9), no Quality Assurance investigation had been completed at the time of inspection and there was no evaluation of the approximately [redacted] on the market.

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e. **There was no Quality Assurance investigation initiated for the discrepancy between the required stability time points as documented in the stability protocol versus the actual time points listed in the electronic stability program. The impact on other stability studies was not assessed. For example:**

i. **The 9-month and 18-month stability stations were not originally included in the electronic stability program for Buspirone HCl Tablets, 5mg, lot# 60502A2, 60502AQ, 70036A2, and 70036AQ. The time points were added on 10/30/07, approximately [redacted] for lot# 60502A2.**

[redacted] (Exh. 8ei1) was initiated on 10/30/07 in order to add the [redacted] stability stations to the electronic stability program for Buspirone HCl Tablets, 5 mg, lot #s 60502A2, 60502AQ, 70036A2 and 70036AQ. The change was requested approximately three weeks after the 9-month stability test date of 10/9/07, for lot # 60502A2 (**Exh 8ei1 p.9**). These time points, which are required in the stability protocol for Buspirone Hydrochloride Tablets USP, 5 mg and 10 mg, (Exh. 8ei2), were originally omitted from the electronic stability program. The stability test intervals entered into the electronic stability program were entered based on a Stability Study Design/Request Form (Exh. 8ei3), which also incorrectly omitted the required [redacted] stability stations. The stability test intervals documented on the Stability Study Design/Request Form are to be pulled directly from the stability protocol and from the filed application. According to Scott Talbot, prior to 8/07, Stability Study Design/Request Forms required no review or approval signatures, nor were the documents formatted with all the [redacted] test intervals that would be needed to populate the electronic stability software. An updated version of the Stability Request Form was provided during the inspection (Exh. 8ei4). No Quality Assurance investigation was conducted in order to determine if any other products were missing required stability test points within the electronic stability program.

ii. **The 18-month stability station was not originally included in the electronic stability program for Drixoral Cold and Allergy ER Tablets, Tablets Lot # 70085A (7-DRT-1) blister pack.**

[redacted] (Exh. 8eii1) was initiated on 11/15/07 in order to add the [redacted] stability station to the electronic stability program for Drixoral Cold and Allergy ER Tablets, lot # [redacted]. This stability time point, which is required in the stability study protocol for Drixoral Cold and Allergy ER Tablets (Exh. 8eii2), was originally omitted from the electronic stability program. The stability test intervals entered into the electronic stability program were entered based on a Stability Study Design/Request Form (Exh. 8eiii3), which also incorrectly omitted the [redacted] The stability test intervals documented on the Stability Study Design/Request Form are to be pulled directly from the stability protocol and from the filed application. According to Scott Talbot, prior to 8/07, Stability Study Design/Request Forms required no review or approval signatures. An updated version of the Stability Request Form was provided during the inspection (Exh. 8ei4). No Quality Assurance investigation was conducted in

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order to determine if any other products were missing required stability test points within the electronic stability program.

f. **No QA investigation was initiated when an operator observed grease visibly trickling off of the tablet press during the compression of Oxycodone HCl USP Tablets, 5 mg, lot# 70761A1 compressed from 9/18/07-9/23/07. [redacted] was subsequently initiated for the lot on 10/3/07 due to the presence of black spots on the tablets, observed during the packaging operation.**

[redacted] (Exh. 8f1) was initiated on 10/3/07 after black spots were identified on some of the tablets during a routine count check performed by a Quality Assurance Technician during the packaging of Oxycodone HCl USP Tablets, 5 mg, Lot # 70761A1 on 9/28/07. A planned deviation, [redacted] (Exh. 8f1 pp. 12-14) was approved by Quality Assurance on 10/19/07, which allowed for the batch to be visually inspected to remove tablets with black spots, to perform an expanded AQL on the tablets remaining after removal of the ones containing black spots, and then to send samples of the tablets containing the black spots to an outside lab for analysis. On 10/30/07, thirty tablets with "dark material on the surface" were received by [redacted] Inc. for identification (Exh. 8f1 p. 22). The conclusions of the analysis were that the "Gray and brown material that was embedded into the tablets consisted of normal tablet materials mixed with aliphatic hydrocarbon-based oil and steel/steel corrosion and brass/brass corrosion particles. The dark material visually appeared to contain larger and more non-uniformly mixed particles of the same type as the normal tablet, and was associated with elevated chlorine and silicon compared to the normal tablet" (Exh. 8f1 p. 23). In a memo to the batch file, dated 2/25/08, (also attached to this investigation) (Exh. 8f1 p. 5), the Manufacturing department noted a possibility that "Food Grade Grease might have built up on the upper punches or the dust cups of the tablet press during the processing of the first batch. It's possible that the grease could have fallen onto the die table and been compressed into the tablets for this batch." Although a similar statement was made in a prior memo to the batch file, dated 10/5/07, (also attached to this investigation) (Exh. 8f1 p. 8), an interview was not conducted with the tablet press operator at that time and the interview was not documented until 2/25/08. The memo documents that "the operator noted that grease was visibly trickling off of the tablet press during the compression operation" (Exh. 8f1 p. 5). No explanation as to why an investigation had not been initiated at the time the operator noted the "grease visibly trickling off the table during compression", nor could an explanation be provided as to why the first documentation of an interview with the operator had not occurred until 2/25/08, more than four months after the black spots had been observed.

We discussed numerous examples of undocumented and untimely Quality Assurance investigations with Ms. Lambridis. A summary of the open and closed QA investigations by product was provided (Exh. 8f2). Ms. Lambridis stated that she was aware of the issue; however she did not currently have the staffing to support the large influx of investigations. We noted our concern about the failure to respond to product quality issues in a timely manner to both Ms. Lambridis and Ms. Eyjolfsdottir, the U.S. and Global Heads of Quality, respectively. At the exit meeting, Mr. Wessman provided a commitment to supply resources to complete the backlog of open Quality Assurance investigations. His commitment was also provided in writing in a letter dated 5/20/08. During the

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inspection we also discussed the need to develop sustainable Quality Systems to facilitate timely and appropriate responses to product quality issues.

Reference: 21 CFR 211.192

Supporting Evidence and Relevance:
Observation 8a: 2b1, 8a1, 2b14-2b16, 2b21
Observation 8b: 3a1, 3a10, 3a3, 3a4, 3a11, 3a18-3a19
Observation 8c: 3f16
Observation 8d: 3i1, 3i9
Observation 8ei: 8ei1-8ei4
Observation 8eii: 8eii1-8eii3, 8ei4
Observation 8f: 8f1-8f2

OBSERVATION 9

Written production and process control procedures are not followed in the execution of production and process control functions and documented at the time of performance.

Specifically,

a. [redacted], dated 11/3/06 requires completion of investigations within [redacted] working days. If an extension is needed, a memo to file describing the progress and the target completion date is required. Numerous Quality Assurance investigations remained open during the inspection including investigations of out of specification finished product and stability out of specification results such as Carisoprodol, Aspirin, and Codeine Phosphate Tablets, USP, lot# 60484A1 initiated 9/4/07, Guanfacine Tablets 2mg, lot#s 5393A2 and 5393A1, initiated 12/11/07. Extension memos were routinely written and approved by the Quality Unit with no justification or description of the investigation progress or potential impact on other product on the market.

[redacted] Investigation of Deviations, dated 11/3/06 describes establishing a, "system for investigating in a timely manner any unplanned deviation (discrepancy). The purpose of the investigation is to determine the assignable cause for the problem, impact on other batches/products, disposition of the product(s) involved and preventive and corrective actions to prevent recurrence of the deviation." (Exh. 9a1). The procedure applies to confirmed out of specification test results for in-process, finished product and stability samples; customer complaints related to quality; deviations from written procedures; and in-process OOS in manufacturing or packaging. Section 5.9 of the SOP requires completion of investigation within [redacted] working days (Exh. 9a1 p. 7). Timeframe extensions require the issuance of an interim memo describing, "the progress made and the target

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date for completion" and must be written [redacted] until the investigation is complete.

During the review of out of specification results for Carisoprodol, Aspirin, and Codeine Phosphate Tablets, USP, lot# 60484A1, (see FDA 483 observation 3a.), we noted that the original out of specification results were obtained on 8/21/07 (**Exh. 3a2 p. 8**). A draft QA investigation [redacted] was provided (**Exh. 3a3**). Although interim memos with the status of the investigation and justification for the timeframe extension are required every [redacted] working days, no interim memo was written until 3/18/08 more than [redacted] after the initial out of specification results were obtained (**Exh. 3a4**). There was also no risk assessment for the potential impact of the product on the market, despite the delay.

The out of specification result was obtained 8/21/07 and a manufacturing issue with the bilayer product was identified 7/20/07 in QA investigation [redacted] (**Exh. 3a11**); however Quality Assurance did not respond to the product on the market until our inspection. During the review of out of specification results for the known degradant 2,6 dichlorophenylacetic acid in Guanfacine Tablets 2mg, lot#s 5393A2 and 5393A1, obtained 11/22/07 (**Exh. 3e12**), the Quality Assurance investigation was requested. A draft QA investigation [redacted] was provided and only included the laboratory results (**Exh. 3e13**). No interim memos were written to include the status of the investigation and justification for the timeframe extension as required every [redacted] working days. Subsequently [redacted] additional stability lots were out of specification for the same known degradant on 2/8/08 and 2/27/08 (**Exh. 3e1, 3e5**) as documented in FDA 483 observation 3e. A draft of the proposed SOP, QC 0033, Rev. 9, Investigation of Deviations (**Exh. 9a2**) was provided by Ms. Lambridis during the inspection.

The failure of the Quality Unit to follow the SOP and meet timeframes resulted in a lack of response to product quality issues. We discussed the incomplete QA investigations throughout the inspection with Ms. Lambridis. At the exit meeting, Mr. Wessman stated that as part of the firm's corrective actions, resources would be provided to complete, review and approve the backlog of QA investigations (**Exh. 8f2**). The commitment for completion of QA investigations was also provided in a letter from Mr. Wessman, dated 5/20/08 (**Exh. 16**).

b[redacted] dated 7/26/07 **does not clearly identify the steps to be taken or samples to be tested by each analyst in an investigation of out of specification or suspect test results. Although solutions are suggested for re-measurement, there is no requirement to evaluate the original tablet grind material when testing a tablet product. Additionally, manufacturing investigations are not initiated at that time of retesting.**

[redacted] Investigation of Out of Specification and Suspect Test Results, dated 7/26/07 (**Exh. 9b1**) was reviewed with [redacted] and Ms. Lambridis, Vice President, U.S. Quality and Compliance. Following the review of the numerous out of specification stability results originally identified; we noted that the current laboratory OOS procedure does not clearly identify the steps to be taken or samples to be tested by

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each analyst in an investigation of out of specification or suspect test results. During review of the multiple OOSN laboratory investigation reports, we noticed that different interpretations of the material to be remeasured and/or retested as well as the quantities varied in the investigations (see FDA 483 observation [redacted]. Although solutions are suggested for re-measurement, there is no requirement to evaluate the original tablet grind material when testing a tablet product. Mr. Zhu stated that traditionally, the approach is to investigate from the original sample back to the original tablet or grind material; however we noticed that retesting is often conducted following remeasurement of the original vial and stock solution. The number of remeasurements and retests also varied between investigations. He agreed that the specific materials to be used, the numbers of remeasurements and retests, and the analysts to test were not always clearly specified in the current procedure, especially for complex investigations. We discussed differences in investigative procedures between a tablet and a capsule due to the availability of a tablet grind for remeasurement. We also discussed the lack of Quality Unit review required prior to a retest. He stated that the procedure was being revised to add clarity and provide greater Quality oversight for Phase II of the investigation. A draft of the proposed [redacted] (Exh. 9b2) was provided by Ms. Lambridis during the inspection.

c. [redacted] dated 10/31/07 requires the filing of a Field Alert within [redacted] working days after receipt of information (confirmed or unconfirmed) for such issues as stability failures or any other significant chemical, physical or other change in a distributed product. The procedure was not followed in that field alerts were not filed within three working days. For example: Phentermine HCl Capsules 30mg, lot# 5436A1 which was filed approximately 9 months after the out of specification stability result and Mirtazapine Orally Disintegrating Tablets, lot# 60794A1 which was filed approximately 3 months after the out of specification stability result.

[redacted] with the FDA, dated 10/31/07 (Exh. 9c1) Section 5.4.1 states, "Within three working days of obtaining the information, the Site Head of Quality or designee must file a Field Alert Form...with the District Office that is responsible for the manufacturing facility." The procedure requires filing of confirmed or unconfirmed issues such as stability failures or any other significant chemical, physical or other change in a distributed product. FDA 483 observation 7a-d documents the failure of the firm to follow [redacted] Field alerts were not filed as per procedure for Phentermine HCl Capsules 30mg, lot# 5436A1 out of specification results were obtained 7/25/07 (Exh. 3b1). The Field Alert was filed during our inspection, approximately [redacted] after the out of specification stability result on 4/24/08 (Att). Out of specification impurity results for a known degradant [redacted] Orally Disintegrating Tablets, lot# 60794A were obtained 1/3/08 (Exh. 3f1). The Field Alert was filed 4/4/08, during our inspection, [redacted] after the out of specification stability result.

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Establishment Inspection Report	FEI:	2244683
Actavis Totowa LLC	EI Start:	03/18/2008
Totowa, NJ 07512	EI End:	05/20/2008

Reference: 21 CFR 211.100(b)

Supporting Evidence and Relevance:
Observation 9a: 9a1, 3a2-3a4, 3a11, 3e12, 3e13, 3e1, 3e5, 9a2, 8f2, 16
Observation 9b: 9b1-9b2
Observation 9c: 9c1, 3b1, 3f1

OBSERVATION 10

Changes to written procedures are not reviewed and approved by the quality control unit.

Specifically,

Changes are not all captured within the formal change control system. Changes that are documented in Work Orders are not reviewed and approved by the Quality Unit. In addition, documentation of justification for changes within the change control system is required by [redacted] but this justification is lacking in detail with respect to product quality. For example:

a. Work Order Forms, which are not reviewed and approved by the Quality Unit, are issued when transferring equipment from one facility to another and when equipment is not functioning properly. For example:

During the inspection, it was noted that the transfer of portable equipment from the Little Falls manufacturing facility to the Riverview Drive manufacturing facility (and vice versa) is documented within Work Orders, which are not reviewed and approved by the Quality Unit. In addition, when equipment is not functioning properly, Work Orders are generated to perform maintenance on the equipment, without an assessment for potential product quality impact or review and approval by the Quality Unit.

i. The Quality Unit did not review and approve [redacted] issued on 12/27/07 and 2/12/08, respectively, to document the transfer of the [redacted] used for the production of Digoxin Tablets, from the Little Falls, NJ manufacturing facility to the Riverview, NJ manufacturing facility. No formal qualification was conducted following the movement of the blender from one site to another.

Work Order #1001 was issued on 12/27/07 to document the transfer of the [redacted] from the Little Falls manufacturing facility to the Riverview Drive manufacturing facility (Exh. 10ail). [redacted] is used in the production of Digoxin Tablets as shown in the Process Validation

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Report for Digoxin Tablets, USP 0.125 mg (**Exh. 10ai2**) and the Equipment Usage and Cleaning Log for the [redacted] (**Exh. 10ai3**). The work order (#1001) was requested by the Director of Operations at Little Falls; the work was performed by Maintenance personnel, and the Work Order was approved by the Director of Operations at Little Falls. The Quality Unit did not review or approve the movement of this equipment. In addition, no formal qualification was conducted following the movement of the blender from one site to the other. A second Work Order, #1039, was issued on 2/12/08 to, again document the transfer of the [redacted] (used for the production of Digoxin Tablets) from the Little Falls manufacturing site to the Riverview Drive manufacturing site (**Exh. 10ai4**). The work order was requested by the Manager of Manufacturing at Little Falls; the work was performed by Maintenance personnel, and the Work Order was approved by the Director of Manufacturing (Little Falls and Riverview). The Quality Unit did not review or approve the movement of this equipment and no formal qualification was conducted following the movement of the blender from one site to the other.

ii. **The Quality Unit did not review and approve [redacted] opened on 3/31/08, to document "the linear scale sensor on the [redacted] is not working". A new sensor was ordered, but no evaluation for potential product impact was made. Vitaplex Tablets, batch# 80249A were manufactured on the equipment from 3/29/08-4/3/08. There is no notation of the work on the production record. Multiple formulations of pediatric prescription vitamins, Multi Vita Bets Tablets were also recently manufactured using the equipment.**

Work Order #1311 was opened on 3/31/08 by Maintenance personnel because "the linear scale sensor on the [redacted] is not working" (**Exh. 10aii1**). A new sensor was ordered, but no evaluation for potential product impact was made. This Work Order document did not route through Quality Assurance for review and approval. According to the Equipment Usage and Cleaning Log, Vitaplex Tablets, batch # 80249A were compressed on this equipment between the dates of 3/29/08 – 4/3/08 (**Exh. 10aii2**). In addition, multiple formulations of pediatric prescription vitamins (Multi Vita-Bets Tablets) had been recently manufactured using this tablet press. At the time of inspection, the new sensor was not installed.

iii. **The Quality Unit did not review and approve [redacted] opened on 4/4/08, to document [redacted] is not working properly". The main bearing was replaced due to this work order, but there was no evaluation for potential product impact. Cyclobenzaprine HCl Tablets, USP 5mg, batch# 80258A was coated 4/1/08-4/4/08 on this equipment and was used for such other products as Prenatal Plus with 27mg Iron Tablets, Dipyridamole Tablets, USP 75mg, and Mirtazapine Tablets, 30mg.**

[redacted] was opened on 4/4/08 because [redacted] is not working properly". (**Exh. 10aiii1**). The main bearing was replaced due to this work order, but there was no evaluation for potential product impact. The work order was requested by the Maintenance personnel; the work was performed by Maintenance personnel, and the Work Order was approved by the Maintenance

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Manager (Little Falls, Riverview and Taft Road). The Quality Unit did not review or approve the work order. [redacted] was used in the coating of Cyclobenzaprine HCl Tablets, USP 5mg, batch # 80258A on 4/1-4/08 as can be seen in the Equipment Usage and Cleaning Log (Exh. 10aiii2 p. 3). This equipment has also been used in the coating of other products including, Prenatal Plus with 27 mg Iron Tablets, Dipyridamole Tablets, USP 75 mg and Mirtazapine Tablets, 30 mg (Exh. 10aiii2).

b. The justification for making changes within the change control system is not documented or is incomplete. For example:

[redacted] (Exh. 10b1) requires that a "description and rationale of proposed change" be documented by the change initiator. Although documentation of justification for changes being made through the change control system is required, this justification is lacking in detail with respect to product quality.

i No justification is included in [redacted] regarding a change in chromatographic column in the analysis of Betaxolol Tablets, USP 10 mg and 20 mg. This change involved the replacement of the chromatographic column used for Assay and Impurity testing. The use of the new column with the existing analytical method resulted in co-elution of chromatographic peaks during impurity testing.

In reviewing [redacted] regarding a change in column in the analysis of Betaxolol Tablets, USP 10 mg and 20 mg it was noted that no justification or rationale was provided for making the change (Exh. 10bi1). The fields for "Description of Change" and "Reason for Change" on the Change Control Request Form are both populated with "Refer "MOI Attachment for list of changes"." The changes listed in the MOI Revision Log included replacing the column used in Assay and Impurity testing from [redacted] (Exh. 10bi1 p. 6). The use of the new column with the existing analytical method resulted in [redacted] of chromatographic peaks during impurity testing. (See observation 5c for details). It was determined that a new analytical method would be required to adequately evaluate the product.

ii Although [redacted] initiated on 3/17/08, was used to remove erroneous calculations which led to the overcharge of Naloxone in Pentazocine and Naloxone Hydrochlorides Tablets USP, 50mg/0.5mg, the justification for the change was not documented in the change control.

[redacted] initiated on 3/17/08, listed the "Description and Rationale of Change" to the master production record for Pentazocine and Naloxone HCl Tablets, USP as "removed calculations of Pentazocine HCl, USP, Naloxone Hydrochloride Dihydrate, USP and Microcrystalline Cellulose, [redacted] Minor format changes made. Added quantity required for Pentazocine HCl, USP, Naloxone Hydrochloride Dihydrate, USP and Microcrystalline Cellulose, 102 NF" (Exh. 2b19). No

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justification was provided to support the change and there is no explanation as to what the change involved. This change involved removing erroneous calculations from the master production record which had resulted in the overcharging of Naloxone HCl in Pentazocine and Naloxone HCl Tablets, USP (all batches manufactured between the dates of 9/8/05 and 3/25/08) (Refer to FDA 483 observation 2b).

iii [redacted] was initiated on 2/20/08 in order to change the container and closure for Hydrocodone Bitartrate and Homatropine Methylbromide Tablets 5mg/1.5mg to address out-of-specification impurity results on stability; however the change control does not include the justification for the proposed change.
*Note: The Change control number was incorrectly documented as [redacted] instead of [redacted]

[redacted] was initiated on 2/20/08 in order to change the container and closure for Hydrocodone Bitartrate and Homatropine Methylbromide Tablets, 5mg/1.5mg (Exh. 10biii1). There is no justification for the change, although the change control had actually been initiated in order to address out-of-specification impurity results received when testing stability batches. This change has not yet been implemented, but was approved by QA, RA, Stability and Packaging.

We discussed the handling of changes using Protocols, Work Orders and Change Control with Ms. Lambridis. We discussed the need for changes that potentially impact product quality to be reviewed and approved by the Quality Unit. We noted the failure to collectively evaluate changes by the Quality Unit and the risk of not assessing potential product impact prior to implementation.

Reference: 21 CFR 211.100(a)

Supporting Evidence and Relevance:
Observation 10ai: 10ai1-10ai4
Observation 10aii: 10aii1-10aii2
Observation 10aiii : 10aiii1-10aiii2
Observation 10b : 10b1
Observation 10bi : 10bi1
Observation 10bii : 2b19
Observation 10biii : 10biii1

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OBSERVATION 11

Drug product production and control records, are not reviewed and approved by the quality control unit to determine compliance with all established, approved written procedures before a batch is released or distributed.

Specifically,

Investigations of Deviation Reports require a review by Quality Assurance, an approval by Regulatory Affairs/Quality Compliance and an approval of product disposition by the Head of Quality Assurance. On multiple occasions, these three signatories were completed by the same individual. For example:

a. [redacted] regarding double thick[redacted] was signed by the Director of Quality Assurance under the sections designated for Quality Assurance, Regulatory Affairs/Quality Compliance and the Head of Quality Assurance.

The Director of Quality Assurance signed under the sections designated for Quality Assurance, Regulatory Affairs/Quality Compliance and the Head of Quality Assurance in the QA investigation [redacted] regarding the "double thick" Digoxin Tablets 0.125 mg , lot # 70924A1/A2 (Exh. 2a1). Refer to FDA 483 observation 2a for details regarding this lot.

b. [redacted] regarding capped tablets observed during the packaging of Oxycodone Hydrochloride Tablets, USP 5 mg, lot # 70976A, was signed by the Director of Quality Assurance under the sections designated for Quality Assurance, Regulatory Affairs/Quality Compliance and the Head of Quality Assurance.

The Director of Quality Assurance signed under the sections designated for Quality Assurance, Regulatory Affairs/Quality Compliance and the Head of Quality Assurance in QA investigation [redacted] regarding capped tablets observed during the packaging of Oxycodone Hydrochloride Tablets, USP 5 mg, lot # 70976A (Exh. 6b1). Refer to FDA 483 Observation 6b for details regarding this lot.

c. [redacted] regarding out of specification assay test results for Carisoprodol, Aspirin & Codeine Phosphate Tablets 200/325/16 mg, lot# 60484A1 at the [redacted] stability station was observed 8/21/07 and was signed by the Director of Quality Assurance on 3/7/08 under the sections designated for Quality Assurance and Regulatory Affairs/Quality Compliance. The section for Product Disposition to be signed by and the Head of Quality Assurance is currently not signed.

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The Director of Quality Assurance signed under the sections designated for Quality Assurance and Regulatory Affairs/Quality Compliance in the QA investigation 07-059 regarding out of specification assay test results for Carisoprodol, Aspirin & Codeine Phosphate Tablets 200/325/16 mg, lot # 60484A1 **(Exh. 3a3).** The section for Product Disposition, to be signed by the Head of Quality Assurance, was not yet signed. Refer to FDA 483 Observation 3a for details regarding this lot.

d. [redacted] **regarding discoloration of Multi Vita-Bets with 1.0 mg Fluoride Tablets, lot #60061A1 at the [redacted] stability station was signed by the Senior Manager Quality & Investigation on 3/25/08 under the sections designated for Quality Assurance, Regulatory Affairs/Quality Compliance and the Head of Quality Assurance.**

The Senior Manager, Quality & Investigation signed under the sections designated for Quality Assurance, Regulatory Affairs/Quality Compliance and the Head of Quality Assurance in the Investigation of QA investigation [redacted] regarding discoloration of Multi Vita-Bets with 1.0 mg Fluoride Tablets, lot # 60061A1 at the [redacted] **(Exh. 11d1).** Lot # 60061A1 failed to meet the specification for description at the 24-month test point due to a color change in the tablets. The tablet color should be "Orange, Pink and Purple", but the observed color for the tablets was "Light Orange, Light Pink and Light Green on the surface. The investigation also noted that "the tablets also showed unpleasant smell." The color change was confirmed by an additional analyst and the root cause for the failure was not identified. A retain of this batch was examined and was found to meet specifications for description. The Senior Manager, Quality & Investigation, concluded that "as the subject batch expired in January 2008, no further action is necessary." The impact on other batches remaining on the market within expiry was not assessed.

Ms. Lambridis stated that she was unaware of the practice and understood the need for multiple levels of review for QA investigations.

Reference: 21 CFR 211.192

Supporting Evidence and Relevance:
Observation 11a: 2a1
Observation 11b: 6b1
Observation 11c: 3a3
Observation 11d: 11d1

REFUSALS

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There were no refusals encountered during the inspection.

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GENERAL DISCUSSION WITH MANAGEMENT

Discussions with management were held throughout the inspection due to the numerous inspectional findings. We, Investigators Zielny and McCaffery informed Phyllis Lambridis, VP U.S. Quality and Compliance and [redacted] of our findings at the site as they were identified on a daily basis. Two additional meetings with the firm's upper management were conducted during the inspection. See "MEETINGS WITH MANAGEMENT" section.

During the inspection, we discussed our limited coverage of Quinapril Hydrochloride and Hydrochlorothiazide Tablets and stated that several potential issues including an incomplete QA investigation on blend uniformity [redacted] as well as atypical dissolution data were observed during our review (Exh. 36). At the exit meeting on 5/20/08, I, Investigator McCaffery stated that our review of the product was not comprehensive, however there were several issues identified that should be further evaluated. Jeffrey Rope, VP Operations, Actavis Totowa. He stated that it was a very important product for the company and would be fully evaluated. In the process validation for Quinapril Hydrochloride and Hydrochlorothiazide Tablets, [redacted] (Exh. 37 pp. 33), the dissolution profile for batch 70955A showed average results of [redacted] Quinapril, including individual results of [redacted] and [redacted] whereas the dissolution release testing of the same batch revealed an average of [redacted] Quinapril at [redacted] with a maximum individual result of [redacted] (Exh. 37 pp. 21, 32). These differences between the two sets of results for the same batch were not further evaluated.

Dissolution Release Testing Single Time Point [redacted] Batch 70955A Quinapril(%)	Dissolution Profile, [redacted] Batch 70955A Quinapril(%) [redacted]
[redacted]	[redacted]
Average [redacted]	

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At the exit meeting on 5/20/08 discussions with management were held prior to the issuance of the FDA 483, Inspectional Observations. Following the discussions with management, the FDA 483, Inspectional Observations was issued to Mr. Robert Wessman, CEO Actavis Group.

Although the firm made commitments for corrective actions in response to our findings during the inspection, there are several areas that remain unaddressed. There are a large number of product lots that were manufactured, tested and released by the same Quality System that failed to document, evaluate and address the product quality issues identified by representative examples in the FDA 483, Inspectional Observations, dated 5/20/08. The inspection did not cover all products, processes, or methods and only covered one of six systems at the facility. The failure of the Quality System and the concern about the quality of other products for which we did not do in depth evaluations was discussed with Mr. Wessman, Mr. Olafsson, Mr. Rope and Ms. Lambridis at the exit meeting. The products manufactured under that failed Quality System remain in question and are both on the market and in the [redacted]

Prior to the exit meeting we had requested a list of all product lots reviewed by the consultants and released by the Quality Unit. At the exit meeting, Ms. Lambridis provided a list of [redacted] and indicated that additional lots had been reviewed and released since the consultants had started on approximately 4/25/08. We discussed the failure to provide the recall documentation to the District Office and the delays in obtaining documents and other information during the inspection, but the ability to provide resources to review and release product to the market in such a short period of time. We expressed our concerns regarding the adequacy of the "risk review" the firm and their consultants conducted for these products. We noted that approximately [redacted] had been released after review by the firm's consultants, although several unresolved product quality issues related to those products were documented on the FDA 483. A list of the lots released following PAREXEL review was provided as Exh. 38. We were notified at the exit meeting that there were [redacted] additional batches that had also been released for a total of [redacted]

We acknowledged the commitment to voluntarily remove the product from the market but noted the Quality Unit's inability to identify and correct problems independently. Ms. Lambridis stated that although resources were needed, they had not been successful at hiring as quickly as they had hoped. We discussed the need not only for additional resources, but for timely science based responses to issues identified.

At the exit meeting we stated to Robert Wessman, CEO that none of the final recall letters or final recall packages had been provided to New Jersey District as of 5/20/08 at the exit meeting, despite our notification to Ms. Lambridis during the inspection that the recall information was needed within [redacted] of notification of the recall. The recall packages had been promised to the New Jersey District Recall Coordinator for two weeks prior to the exit meeting. Ms. Lambridis stated that four of the recall packages would be provided to the District on 5/21/08 and that the remaining recall packages from the first group of products recalled would be provided to the District by 5/23/08.

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Mr. Wessman gave a verbal commitment at the exit meeting to discontinue the release of any additional batches until further discussions are held with the District; improve the infrastructure of the firm's quality system; provide the district with a timeframe for completing the "risk reviews" of the products remaining on the market; aggressively work to close the many open investigations; and resume manufacturing one process at a time. He provided a written commitment later that day confirming this commitment.

ADDITIONAL INFORMATION

Although Mr. Wessman committed to temporarily discontinuing the release of lots based on a paper review conducted by the consultants for the products in the distribution centers, he did not commit to removal of the other lots that remain on the market which were manufactured, analyzed and released by a failed Quality System. A comprehensive list of products remaining on the market was requested at the exit meeting and provided by Ms. Lambridis after the inspection (Exh. 39).

The responses to all findings throughout the inspection were reactive and not proactive. At the initiation of the inspection, the firm had more than [redacted] for which confirmed stability failures were documented and confirmed by their laboratory. The Quality Unit had not responded to any of the failures to remove the out of specification product from the marketplace. No recalls were initiated in response to the failures at the initiation of the inspection on 3/18/08. The first recalls were initiated after extensive discussions of the violations and a request for interstate documentation for the out of specification stability lots. Additional recalls were initiated based on our continued findings and the findings of consultants who were hired as part of the firm's corrective action plan. We acknowledged the commitment to voluntarily remove the product from the market but noted the Quality Unit's inability to identify and correct problems independently. Ms. Lambridis stated that although resources were needed, they had not been successful at hiring as quickly as they had hoped. We discussed the need not only for additional resources, but for timely science based responses to issues identified.

We were notified of the initial recalls on 4/4/08; however on 5/2/07 the product remained on the market. We questioned the date that the recall letters were sent. Ms. Lambridis contacted Capital Returns, the contractor facilitating the recall. She determined that the recall letters had not been sent. She stated that Actavis was delayed in providing the letters and therefore delayed Capital Return's mailing. We were notified 5/7/08, approximately one month after the commitment to recall products that the recall letters were sent. At the exit meeting we stated to Robert Wessman, CEO that none of the final recall letters or final recall packages had been provided to New Jersey District as of 5/20/08 at the exit meeting, despite our notification to Ms. Lambridis during the inspection that the recall information was needed within [redacted] of notification of the recall. We also discussed the use of resources to attempt to release additional products when the recall information still had not been provided to the District and the Quality System failures had not been fully assessed. The recall packages were promised to the New Jersey District Recall Coordinator for two weeks prior to the exit meeting. Ms. Lambridis stated that four of the recall packages would be

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provided to the District on 5/21/08 and that the remaining recall packages from the first group of products recalled would be provided to the District by 5/23/08.

Prior to the exit meeting we requested a list of all product lots reviewed by the consultants and released by the Quality Unit. Ms. Lambridis provided a list of [redacted] (Exh. 38) and indicated that additional lots had been reviewed and released. We discussed the failure to provide the recall documentation to the District Office but the ability to provide resources to release product to the market. Mr. Wessman gave a verbal commitment at the exit meeting to discontinue the release of any additional batches until further discussions are held with the District. He provided a written commitment later that day confirming his commitment.

We requested interstate documentation for [redacted] which had documented cGMP violations. We requested the information on 4/17/08 and provided additional product specific requests on 4/22/08. On 5/15/08, when the affidavits were issued, there were still outstanding shipping documents from the original request. Daniel Bitler, Director of Quality Assurance stated that shipping is not his area of responsibility and asked us what we wanted him to do if he could not obtain all the records requested. We explained that custody and conditions under which the active pharmaceutical ingredients were held, should be assured by Quality due to their use in marketed finished products. We stated that we would collect the documentation which was available for inspection and note any missing documents in the affidavits (FDA 463a).

SAMPLES COLLECTED

No physical samples were collected during the inspection; however documentary samples were collected to demonstrate interstate commerce and to provide examples of products released by the firm's Quality Unit despite cGMP deficiencies.

On 5/15/08, eleven FDA 463a, Affidavits were presented to Daniel Bitler, Director, Quality Assurance, Totowa, LLC for the following Documentary Samples:

-DOC 419934: Carisoprodol, Aspirin, Codeine Phosphate Tablets USP, 200 mg/325mg/16mg, Lot # 60484A1 (Please refer to FDA 483 Observation 1, 3a, 8b, 9a, 11c.)

-DOC 419935: Digitek (Digoxin Tablets, USP), 0.125 mg, Lot # 70924A1/A2 (Please refer to FDA 483 Observation 1, 2a, 6a, 11a.)

-DOC 419936: Amantadine Hydrochloride Capsules, USP 100 mg, Lot # 60324A1 (Please refer to FDA 483 Observation 1, 3d, 5e.)

-DOC 419937: Phentermine Hydrochloride Capsules USP, 30 mg, Lot # 5704A1 (Please refer to FDA 483 Observation 1, 3b, 7a.)

-DOC 419938: Oxycodone Hydrochloride Tablets, USP 30 mg, Lot # 80255A1 (Please refer to FDA 483 Observation 1.)

-DOC 467811: Phentermine Hydrochloride Capsules USP, 37.5 mg, Lot # 70996A1 (Please refer to FDA 483 Observation 1.)

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-DOC 467812: Betaxolol Tablets, USP, 10 mg, Lot # 60215A1 (Please refer to FDA 483 Observation 1, 5c.).

-DOC 467813: Mirtazapine Orally Disintegrating Tablets, 30 mg, Lot # 70421A1 (Please refer to FDA 483 Observation 1, 3f, 8c.)

-DOC 467814: Digitek (Digoxin Tablets, USP), 0.125 mg, Lot # 71005A1 (Please refer to FDA 483 Observation 1, 2a, 6a., 11a.)

-DOC 467815: Pentazocine and Naloxone Hydrochlorides Tablets, USP, 50mg(base)/0.5mg(base), Lot # 80016A1 (Please refer to FDA 483 Observation 1, 2b, 8a.)

-DOC 470185: Hydrocodone Bitartrate and Homatropine Methylbromide Tablets, 5mg/1.5mg, Lot # 5683A1 (Please refer to FDA 483 Observation 1, 3c.)

I, Investigator Zielny, asked Mr. Bitler to read and verify the accuracy of the Affidavits and to compare them to the documents that were provided. Mr. Bitler agreed to read the Affidavits, but stated that he would not sign the documents under the direction of Ms. Phyllis Lambridis. SOP # 0041: Procedures for FDA Inspections (**Exh. 40**) was provided which states not to participate in anything having to do with an Affidavit. Mr. Bitler verified [redacted] that he could read and verify the accuracy of the contents of the Affidavits.

All Affidavits for the above listed documentary samples were read and verified by Mr. Daniel Bitler, Director, Quality Assurance on 5/15/08. Mr. Bitler made corrections by hand when necessary and initialed and dated each correction.

An additional Documentary Sample, DOC 377415, was collected at [redacted] to show the distribution of [redacted] DOC 419934 shows the receipt of active pharmaceutical ingredients at Actavis Totowa LLC, the production of Lot # 60484A1, the release of the lot and the shipment of the lot to [redacted] shows the distribution of the lot from [redacted] Inc to multiple wholesale distributors. On 5/9/08, an Affidavit was presented to Mr. Walter Cespedes, Senior Director, Quality Assurance, at [redacted] who reviewed the document and verified the accuracy of the document. Mr. Cespedes signed the affidavit on 5/9/08, and confirmed that the content of the document is true and accurate to the best of his knowledge.

VOLUNTARY CORRECTIONS

Significant changes in upper management of the site were initiated during the inspection. The organizational changes were identified by the firm following a meeting on 4/23/08 during the inspection which is documented in a commitment letter dated 4/28/08 (**Exh. 14**). Additionally a commitment to voluntarily recall more than [redacted] of product was obtained during the inspection (**Att**). The firm acknowledged all findings and the need for substantial corrective actions. A consulting company, PAREXEL, was retained during the inspection to assess the Quality deficiencies. At the exit meeting Mr. Wessman and Mr. Olafsson stated that the corrective action

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plans would be provided to the District. Their commitments are documented in "ADMINISTRATIVE DATA", "ADDITIONAL MEETINGS WITH MANAGEMENT", "GENERAL DISCUSSION WITH MANAGEMENT" and "ADDITIONAL INFORMATION" sections of this report.

EXHIBITS COLLECTED

Exhibit Listing

Please note that there is no exhibit "1".

2a1. Investigation [redacted] Digoxin Tablets 0.125mg, Batch 70924A1, Approved 1/25/08, 68 pages.

2a2. Executed Batch Record, Digoxin Tablets, 0.125mg, Batch 70924A, Approved 12/04/07, 138 pages.

2a3. Digoxin Tablets 0.125mg Batch 70924A compression release, bulk product disposition, labeling release, and finished product release dated 11/21/07, 6 pages.

2a4. Health Hazard Evaluation, Digoxin Tablets 0.125mg, 70924A1 dated 4/18/08, 2 pages.

2b1. Investigation [redacted] Pentazocine hydrochloride & Naloxone hydrochloride Tablets, Batch/Lot 70053A2, 60397A1, and 70053AQ, approved 2/2/08, 9 pages.

2b2. Laboratory Test Report, Stability Drug Product, Pentazocine HCl & Naloxone HCl Tablets, Batch 70053A2, approved 8/19/02, 12 pages.

2b3. Data Acquisition Using [redacted] Pentazocine HCl & Naloxone HCl Tablets, Assay, [redacted] checked 1/3/08, 30 pages.

2b4. Data Acquisition Using [redacted] Pentazocine HCl & Naloxone HCl Tablets, Limit Test, [redacted] l, 10 pages.

2b5. Original Analysis, [redacted] Pentazocine HCl & Naloxone HCl Tablets, Batch 70053A2 & 60397A1, completed 1/3/08, 13 pages.

2b6. Re-measurement Study, [redacted] Pentazocine HCl & Naloxone HCl Tablets, Batch 70053A2 & 60397A1, completed 1/4/08, 11 pages.

2b7. Data Acquisition Using [redacted] Pentazocine HCl & Naloxone HCl Tablets, Assay, [redacted] re-measurement, checked 1/7/08, 40 pages.

2b8. Data Acquisition Using [redacted] Pentazocine HCl Naloxone HCl Tablets, Limit Test, [redacted] re-measurement, checked 1/19/08, 10 pages.

2b9. Repeat Test I, [redacted] entazocine HCl & Naloxone HCl Tablets, Batch 70053A2, 60397A1, completed 1/12/08, 8 pages.

2b10. Data Acquisition Using [redacted] Pentazocine HCl & Naloxone HCl Tablets, [redacted] Assay, repeat test I, checked 1/26/08, 28 pages.

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2b11. Data Acquisition Using [redacted] Pentazocine HCl & Naloxone HCl Tablets, [redacted] Limit test, repeat test I, checked 1/26/08, 9 pages.

2b12. Data Acquisition Using [redacted] Pentazocine HCl & Naloxone HCl Tablets, [redacted] Assay, Phase II Investigation, 30 pages.

2b13. MPR Request/Change Control Form and Master for Pentazocine & Naloxone HCl Tablets, dated 12/13/04, 16 pages.

2b14. MPR Request/Change Control Form and Master Formula for Pentazocine & Naloxone HCl Tablets, dated 9/6/05, 17 pages.

2b15. MPR Request/Change Control Form and Master Formula for Pentazocine & Naloxone HCl Tablets, dated 8/9/06, 17 pages.

2b16. MPR Request/Change Control Form and Master Formula for Pentazocine & Naloxone HCl Tablets, dated 2/17/07, 20 pages.

2b17. [redacted] Pentazocine & Naloxone HCl Tablets, Approved 9/5/05, 9 pages.

2b18. MPR Request/Change Control Form and Master Formula for Pentazocine & Naloxone HCl Tablets, dated 3/17/08, 15 pages.

2b19. [redacted] Pentazocine & Naloxone HCl Tablets, approved 3/25/08, 5 pages.

2b20. Batches Pentazocine & Naloxone HCl Tablets within expiration date, 2 pages.

2b21. [redacted] Follow-up Pentazocine/Naloxone Tablets, 11 pages.

2b22. [redacted] Pentazocine HCl & Naloxone HCl Tablets, dated 8/25/2007, 14 pages.

2b23. Toxicity Calculation, Pentazocine & Naloxone Tablets, 1 page.

2b24. Summary Formulation Error in Pentazocine & Naloxone HCl Tablets, 1 page.

2b25. Notebook, Pentazocine HCl & Naloxone HCL Tabs, [redacted] 11 pages.

3a1. [redacted] Carisoprodol, Aspirin & Codeine Tablets, Batch # 60484A1, dated 9/6/07, 7 pages.

3a2. Laboratory Worksheet, Book 0033, Carisoprodol, Aspirin & Codeine Tablets, date 8/28/07, 8 pages.

3a3. Deviation Report, Investigation [redacted] Carisoprodol, Aspirin & Codeine Phosphate Tablets 200/323/16 mg, Product Lot No. 60484A1, [redacted]

3a4. Interim Report for Investigation, Investigation [redacted] dated 3/19/08, 1 page.

3a5. [redacted] Carisoprodol, Aspirin & Codeine Tablets, Batch # 604841, CRT 18M-100's, dated 2/13/08, 3 pages.

3a6. Laboratory Worksheet, Book 0033, Carisoprodol, Aspirin & Codeine Tablets, date 8/28/07, 5 pages.

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3a7. Investigation [redacted] Carisoprodol, Aspirin & Codeine Tablets, Batch # 60484A1, [redacted] dated 1/16/0895, 95 pages

3a8. [redacted] Investigation Addendum, [redacted] Carisoprodol, Aspirin & Codeine Tablets, 200 mg/325 mg/16 mg, Batch # 60484A1, dated 2/13/08, 3 pages.

3a9. A listing entitled "Batches Within Expiration Date" Carisoprodol, Aspirin & Codeine Tablets, 200 mg/325 mg/16 mg, 1 page.

3a10. [redacted] Carisoprodol, Aspirin & Codeine Tablets, Batch # 70484A, Assay and CU, dated 10/8/07, 32 pages.

3a11. Investigation of Deviation Report [redacted] Batch # 70484A, Carisoprodol, Aspirin & Codeine Tablets, 200 mg/325 mg/16 mg, date initiated 7/20/07, 67 pages.

3a12. [redacted] Investigation Addendum, Carisoprodol, Aspirin & Codeine Tablets, 200 mg/325 mg/16 mg, [redacted] date approved 1/22/08, 6 pages.

3a13. Assay Results of Carisoprodol, Aspirin & Codeine Tablets, 200 mg/325 mg/16 mg. Retain Samples, 1 page.

3a14. Laboratory Worksheet, [redacted] Carisoprodol, Aspirin & Codeine Tablets, 200 mg/325 mg/16 mg, dated 9/22/07, 15 pages.

3a15. Laboratory Worksheet, [redacted] Carisoprodol, Aspirin & Codeine Tablets, 200 mg/325 mg/16 mg, dated 9/22/07, 33 pages.

3a16. Laboratory Worksheet, [redacted], for [redacted] Carisoprodol, Aspirin & Codeine Tablets, 200 mg/325 mg/16 mg, dated 10/22/07,10 pages.

3a17. Process Validation Report, Carisoprodol, Aspirin & Codeine Tablets, [redacted] Tablets, MFR [redacted] 86 pages.

3a18. Batch Record Hold, Issuance of Carisoprodol, Aspirin and Codeine Phosphate Tablets, USP 200mg/325 mg/16 mg (138), 1 page.

3a19. Batch Record Hold, Issuance of Carisoprodol and Aspirin Tablets USP 200 mg/325 mg, 1 page.

3a20. [redacted] Carisoprodol, Aspirin and Codeine Phosphate Tablets, USP 200mg/325mg/16mg (138), Batch #70702A, 6 pages.

3a21. [redacted] Carisoprodol and Aspirin Tablets USP 200mg/325mg (137), Batch #70668A, 5 pages.

3b1. [redacted] Phentermine HCl Capsules, 300 mg, date initiated 7/25/07, 22 pages.

3b2. Laboratory Worksheet [redacted] Phentermine HCl Capsules, 300 mg, dated 7/27/2007, 6 pages.

3b3. Data Acquisition (chromatograms, original run) for [redacted] for Phentermine HCl Capsules, 300 mg, Batch # 5436A1, A2, dated 7/26/2007, 33 pages.

3b4. Data Acquisition (chromatograms, Re-measure) for [redacted] for Phentermine HCl Capsules, 300 mg, Batch # 5436A1, A2, dated 7/26/2007, 38 pages.

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3b5. Data Acquisition (chromatograms, Repeat) for [redacted] or Phentermine HCl Capsules, 300 mg, Batch # 5436A1, A2, dated 7/27/2007, 29 pages.

3b6. Investigation of Deviation Report, Phentermine HCl Capsules 30 mg, Batch # 5436A1 and 5436A2, [redacted] dated initiated 9/14/07, 34 pages.

3b7. Summary of stability study purpose, 1 page.

3b8. [redacted] Phentermine HCl Capsules 30 mg, Batch # 5704AQ (CRT 24 M- 100's), date initiated 12/8/07, 7 pages.

3b9. Laboratory Worksheet, [redacted] for Phentermine HCl Capsules 30 mg, Batch # 5704AQ, A1, dated started 11/30/07, 5 pages.

3b10. Data Acquisition (chromatograms) for [redacted] or Phentermine HCl Capsules, 300 mg, Batch # 5704AQ, A1, dated 12/03/2007, 85 pages.

3b11. Investigation of Deviation Report, Phentermine HCl Capsules 30 mg, Batch # 5704AQ, for [redacted], date initiated 12/11/07, 5 pages.

3b12. A listing for DESI products manufactured by facility, 6 pages.

3c1. Data Acquisition (chromatograms) for [redacted] Hydrocodone bitartrate and Homatropine methylbromide Tablets, Batch # 5683A1, (RT 24 M/100's pk), dated 11/13/07, 3 pages.

3c2. Laboratory notebook for assay of Hydrocodone bitartrate and Homatropine methylbromide Tablets, Batch # 5683A1, 7 pages.

3c3. Data Acquisition (chromatograms) (original run) for [redacted] Hydrocodone bitartrate and Homatropine methylbromide Tablets, Batch # 5683A1, dated 11/13/2007, 24 pages.

3c4. Data Acquisition (chromatograms) (original run) for [redacted] Hydrocodone bitartrate and Homatropine methylbromide Tablets, Batch # 5683A1, dated 11/15/2007, 35 pages.

3c5. Data Acquisition (chromatograms) (original run) for [redacted] Hydrocodone bitartrate and Homatropine methylbromide Tablets, Batch # 5683A1, (Repeat test), dated 11/15/2007, 31 pages.

3c6. [redacted] Investigation Addendum for [redacted] Hydrocodone bitartrate and Homatropine methylbromide Tablets, Batch # 5683A1, 35 pages.

3c7. Investigation of Deviation Report, Hydrocodone bitartrate and Homatropine methylbromide Tablets, [redacted] 49, Batch # 5683A1, dated initiated 11/15/07, 8 pages.

3c8. Investigation Plan for Hydrocodone bitartrate and Homatropine methylbromide Tablets, Batch # 5683A1, dated initiated 11/15/07, 3 pages.

3c9. Interim Report for Investigation, Hydrocodone bitartrate and Homatropine methylbromide Tablets 5mg/1.5mg, Batch # 5683A1, dated initiated 3/19/08, 1 page.

3c10. [redacted] for Hydrocodone bitartrate and Homatropine methylbromide Tablets, Batch # 60437A1, Batch # 60437A1 (CRT/18M/100's), date initiated 12/26/07, 3 pages.

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3c11. Laboratory Worksheet, [redacted] Hydrocodone bitartrate and Homatropine methylbromide tablets, Batch # 60437A1, dated 12/22/07, 8 pages.

3c12. Data Acquisition (chromatograms) Hydrocodone bitartrate and Homatropine methylbromide Tablets, [redacted] Batch # 60437A1, dated 12/27/07, 35 pages.

3c13. Data Acquisition (chromatograms-original run) Hydrocodone bitartrate and Homatropine methylbromide Tablets, [redacted] Batch # 60437A1, dated 12/28/07, 26 pages.

3c14. Data Acquisition (chromatograms-repeat test) Hydrocodone bitartrate and Homatropine methylbromide Tablets, [redacted] Batch # 60437A1, dated 12/31/07, 33 pages.

3c15. [redacted] Investigation Addendum, Hydrocodone bitartrate and Homatropine methylbromide Tablets, 1.5/5mg Tablets, [redacted] Batch # 60437A1, 3 pages.

3c16. Investigation of Deviation Report, Hydrocodone bitartrate and Homatropine methylbromide Tablets, 5mg/1.5mg Tablets, [redacted], Batch # 60437A1, 5 pages.

3c17. Interim Report Investigation, Hydrocodone bitartrate and Homatropine methylbromide Tablets, 5mg/1.5mg Tablets, [redacted] Batch # 60437A1, 4 pages.

3c18. Method of Instruction [redacted] Evaluation of Hydrocodone Bitartrate and Homatropine Methylbromide Tablets HPLC Assay and Related Substances Methods, 7 pages.

3c19. "Document Detail" method of analysis regarding Hydrocodone Bitartrate and Homatropine Methylbromide Tablets HPLC Assay and Related Substances Methods, 18 pages.

3c20. Investigation of Three Impurity Peaks in Chromatogram of Hydrocodone Bitartrate and Homatropine Methylbromide Tablets, Batch 5683A1, dated 3/17/08, 30 pages.

3c21. Toxicity Calculation, Hydrocodone Bitartrate (5 mg) and Homatropine Methylbromide Tablets (1.5 mg), 10 pages.

3c22. A listing entitled, "Batches within Expiration Date" 1 page.

3c23. Laboratory Test Report, Stability Drug Report, Hydrocodone bitartrate & Homatropine methylbromide Tablets, 2 pages.

3d1. [redacted] Investigation Addendum [redacted] Amantadine HCl Capsules, 100 mg, Batch # 60324A1, (Assay/CRT 18M/100's pk.), 3 pages.

3d2. [redacted] Investigation Addendum [redacted] Amantadine HCl Capsules, 100 mg, Batch # 60324A1, OOS Low Assay Result [redacted] 4 pages.

3d3. Laboratory Worksheet [redacted] Amantadine HCl Capsules, 100 mg, dated 12/3/07, 12/4/07, 8 pages.

3d4. Data Acquisition (chromatograms-original) [redacted] Amantadine HCl Capsules, 100 mg, Batch # 60260 A1, AQ, 60325A1, AQ, 60324A1, AQ, 36 pages.

3d5. Data Acquisition (chromatograms-remeasurement) [redacted] Amantadine HCl Capsules, 100 mg, Batch # 60324A1, dated 12/5/07, 22 pages.

3d6. Data Acquisition (chromatograms-repeat) [redacted] Amantadine HCl Capsules, 100 mg, Batch # 60324A1, dated 12/7/07, 22 pages.

3d7. Investigation Deviation Report, Amantadine HCl Capsules, 100 mg, Batch

#60324A1 [redacted] date initiate 1/10/08, 4 pages.

3d8. Interim Report for Investigation for Amantadine HCl Capsules, 100 mg, Batch # 60324A1, dated 2/8/08, 1 page.

3d9. Interim Report for Investigation for Amantadine HCl Capsules, 100 mg, Batch # 60324A1, dated 3/19/08, 1 page.

3d10. A listing entitled as "Batches Within Expiration Date" , 1 page.

3d11. A "Document Detail" for Amantadine HCl Capsules, 100 mg, Method of Analysis, 16 pages.

3d12. Method Remediation Progress Report for Amantadine HCl Capsules, 100 mg, dated 3/26/08, 4 pages.

3d13. Laboratory Worksheet, Book # 0091, dated 1/10/08, 1 page.

3e1. [redacted] Guanfacine Tablets 2mg, 1 mg, dated 2/27/08, 3 pages.

3e2. [redacted] Investigation Addendum for [redacted] Guanfacine Tablets, Batch # 60956A (2 mg), Batch # 60126A and 60126AQ (1 mg), [redacted]

3e3. Laboratory Worksheet [redacted] Guanfacine Tablets, dated 2/26/08, 9 pages.

3e4. Data Acquisition (chromatograms-original run) [redacted] Guanfacine Tablets 2 mg and 1 mg, dated 2/27/08, 113 pages.

3e5. [redacted] Guanfacine Tablets, Batches # 70012A2 and # 70012A1, date initiated 2/8/08, 3 pages.

3e6. [redacted] Investigation Addendum, [redacted] Guanfacine Tablets, Batches # 70012A1 and # 70012A1, 4 pages.

3e7. Laboratory Worksheet [redacted] Guanfacine Tablets 1 mg, dated 2/7/08, 5 pages.

3e8. Data Acquisition (chromatograms-original run) [redacted] Guanfacine Tablets 1 mg, Batches # 70012A1 and # 70012A1, dated 2/8/08, 75 pages

3e9. Investigation of Deviation Report [redacted] Guanfacine Tablets 1 mg, Batches # 70012A1 and # 70012A1, (12 Months, CRT), dated 2/14/08, 1 page.

3e10. Justification Report to Propose Revised Limit of 2,6-Dichlorophenylacetic Acid, Guanfacine Tablets, USP 1 mg and 2 mg, (no date), 5 pages.

3e11. Abstract for Guanfacine Tablets, Limits for 2,6-Dichlorophenylacetic Acid, 6 pages.

3e12. [redacted] Guanfacine Tablets, 2 mg, Batch # 5393A2, A1, date initiated 11/22/07, 8 pages.

3e13. Investigation of Deviation Report, [redacted] Batches # 5393A1, 5393A2, Guanfacine 2.0 mg Tablets, date initiated 12/11/07, 5 pages.

3e14. A listing noting "Batches Within Expiration Date", Guanfacine Tablets 1 mg, 2 pages.

3f1. [redacted] Mirtazapine OD Tablets, 15 mg, 30 mg, Batch #60795A1, 4 pages.

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3f2. Copy OOS/STR Investigation Addendum, [redacted] Mirtazapine OD Tablets, 15 mg, 30 mg, Batches # 60794A1, 60795A1, 5 pages.

3f3. Laboratory Worksheet, [redacted] Mirtazapine OD Tablets, 15 mg, 30 mg, 8 pages.

3f4. Data Acquisition (chromatograms-original run), [redacted], Mirtazapine OD Tablets, 15 mg, 30 mg, Batches # 60794A1, 60795A1, dated 1/3/08, 31 pages.

3f5. Data Acquisition (chromatograms/re-measurement run), [redacted] Mirtazapine OD Tablets, 15 mg, 30 mg, Batches # 60794A1, 60795A1, dated 1/7/08, 38 pages.

3f6. Data Acquisition (chromatograms/Repeat Test), [redacted] Mirtazapine OD Tablets, 15 mg, 30 mg, Batches # 60794A1, 60795A1, dated 1/9/08, 36 pages.

3f7. Data Acquisition (chromatograms/Repeat Test), [redacted] Mirtazapine OD Tablets, 15 mg, 30 mg, Batches # 60794A1, 60795A1, (CRT/15 M, blister), dated 1/07/08, 54 pages.

3f8. Data Acquisition (chromatograms/Repeat Test), [redacted] Mirtazapine OD Tablets, 15 mg, 30 mg, Batches # 60794A1, 60795A1, (RT/15M), dated 1/07/08, 69 pages.

3f9. Justification for Extension for [redacted] Mirtazapine OD Tablets, 15 mg, 30 mg, Batches # 60794A1, 60795A1, (OOS/Impurity Results), dated 3/19/08, 1 page.

3f10. [redacted], Mirtazapine OD Tablets, dated 2/26/08, 3 pages.

3f11. [redacted] Investigation Addendum [redacted] Mirtazapine OD Tablets, Batch 70279A1 and 70420A1 (15 mg) and 70421A1 (30 mg), 5 pages.

3f12. Laboratory Worksheet, [redacted] Mirtazapine OD Tablets, dated 2/25/08, 11 pages.

3f13. Data Acquisition (chromatograms-original), [redacted] Mirtazapine OD Tablets, Batches # 70279A1, # 70420A2, # 70421A1, # 70281A1, # 70895A1, dated 2/26/08, 41 pages.

3f14. Data Acquisition (chromatograms/Re-measurement), [redacted] Mirtazapine OD Tablets, Batches # 70279A1, # 70420A2, # 70421A1, # 70281A1, # 70895A1, dated 2/28/08, 72 pages.

3f15. Data Acquisition (chromatograms/Retest), [redacted] Mirtazapine OD Tablets, Batches # 70279A1, # 70420A2, # 70421A1, dated 2/28/08, 43 pages.

3f16. Investigation of Deviation Report [redacted] Mirtazapine OD Tablets, Batches # 70279A1 [redacted] # 70420A2 [redacted], # 70421A1 [redacted] dated 2/28/08, 1 page.

3f17. Investigation of Deviation Report, [redacted] Mirtazapine OD Tablets, Batches # 70279A1 (15 mg), # 70420A2 (15 mg), # 70421A1 (30 mg), # 60794A1 (15 mg), 60795A1 (15 mg) 60796A1 (30 mg), dated 2/28/08, 17 pages.

3f18. A listing noting "Batches Within Expiration Date", Mirtazapine OD Tablets 15 mg, 2 pages.

3f19. A listing noting "Batches Within Expiration Date", Mirtazapine OD Tablets 45 mg, 1 page.

3f20. Letters between Actavis and FDA, discussing a proposed CBE-30 day Supplement for [redacted] for Mirtazapine OD Tablets 15 mg, 30 mg, 45 mg, letters dated 11/20/07 and 9/4/07, 4 pages.

3f21. Stability Drug Product-Test Report, Mirtazapine OD Tablets, 15 mg, dated 3/24/05, 6 pages.

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3f22. Investigation Report, Mirtazapine OD Tablets, 15 mg and 30 mg, (Reference: QA Investigation [redacted] QC OOSN 07-083 & OOSN 07-085), 15 pages.

3g1. Copy Investigation [redacted] GlyburideTablets, Batches 60164A & 60164AQ, Approved 12/3/07, 15 pages.

3g2. [redacted] Glyburide Tablets analysis, completed 10/4/07, 11 pages.

3g3. Data Acquisition Using [redacted] System GlyburideTablets, Batches 60164A1, 70200A1, Checked 10/9/07, 51 pages.

3g4. Data Acquisition Using [redacted] System GlyburideTablets, Batch 60164A1, Checked 10/9/07, 56 pages.

3g5. Data Acquisition Using [redacted] System GlyburideTablets, Batches 60164A1 & 60164 AQ, Checked 10/9/07, 41 pages.

3g6. Data Acquisition Using [redacted] System GlyburideTablets, Batch 60164A1, Checked 10/11/07, 51 pages.

3g7. Investigation [redacted] Glyburide Tablets Batches 60164A1 & 60164AQ, 12/21/07, 83 pages.

3g8. Justification Report for Revised Limit of Glyburide Related Compounds, Approved 12/21/07, 12 pages.

3g9. [redacted] Glyburide Tablets, Prior Approval Supplement, dated 1/3/2008, 2 pages.

3g10. Investigation [redacted] Glyburide Tablets Batches 60170AQ & 60170A1, dated 3/26/08, 3 pages.

3g11. Investigation Addendum [redacted] Glyburide Tablets Batches 60170AQ & 60170A1, 4 pages.

3g12. [redacted] Glyburide Tablets analysis, Batch 70200A, 70197A2, 60170AQ & 60170A1, 3/25/08, 15 pages.

3g13. Data Acquisition using Empower, Glyburide Tablets Batches 70200A, 70197A2, 60170AQ & 60170A1, Checked 3/26/08, 59 pages.

3g14. Data Acquisition using Empower, Re-measurement run, Glyburide Tablets Batches 70200A, 70197A2, 60170AQ & 60170A1, Checked 3/28/08, 92 pages.

3g15. Data Acquisition using Empower, Repeat test, Glyburide 60170 AQ, Checked 3/28/08, 48 pages.

3g16. Preliminary Investigation, Investigation [redacted] initiated 4/7/08, 10 pages.

3g17. Glyburide Tablets 1.5mg Batches within Expiration Date, 2 pages.

3g18. Glyburide Tablets 6mg Batches within Expiration Date, 1 page.

3h1. [redacted] Investigation Addendum, [redacted] Chlordiazepoxide HCl and Clidinium Bromide Capsules, 5 mg/2.5 mg, Batch # 5553A3 [redacted], 10 pages.

3h2. Laboratory Worksheet, Chlordiazepoxide HCl and Clidinium Bromide Capsules, dated 8/2/07, 9 pages.

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3h3. Investigation of Deviation Report, Investigation [redacted] and [redacted] for Chlordiazepoxide HCl and Clidinium Bromide Capsules, Batches [redacted], dated initiated 9/12/07, 42 pages.

3h4. Investigation of Out-of-Specification and Suspect Test Result [redacted] dated 1/8/07, 29 pages.

3h5. Laboratory Worksheet, Chlordiazepoxide HCl and Clidinium Bromide Capsules, Batch # 5553A3, dated 8/10/07, 5 pages.

3h6. Data Acquisition sheets (chromatograms), Batch 5553A3, Chlordiazepoxide HCl and Clidinium Bromide Capsules, dated 8/15/07,19 pages.

3h7. Investigation (impurity peak) Chlordiazepoxide HCl (5 mg)/Clidinium Bromide (2.5 mg) Capsules, Batch # 3480A3, 22 pages.

3h8. Chlordiazepoxide HCl (5 mg)/Clidinium Bromide Capsules, Retain Batch Testing Surveillance Protocol, 5 pages.

3h9. Chlordiazepoxide HCl and Clidinium Bromide Capsules, Retain Sample Assay Result, 1 page.

3h10. A listing for "Batches within Expiration Date" Chlordiazepoxide HCl and Clidinium Bromide Capsules, 1 page.

3h11. List of Products without Impurity Tests in Stability Specifications, 1 page.

3h12. Finished Product Stability-Test Report, Chlofdiazepoxide HCl and Clidinium Bromide Capsules, USP, dated 3/27/08, 2 pages.

3i1. [redacted] Multiret Folic 500 mg Tablets, Batch # 70607A1, (CRT/ 3M/blister), 3 pages.

3i2. Laboratory Worksheet, [redacted] Multiret Folic 500 mg Tablets, Batch # 70607A1, dated 1/7/08, 12 pages.

3i3. Data Acquisition sheets (chromatograms-original), [redacted] Multiret Folic 500 mg Tablets, [redacted], 16 pages.

3i4. Data Acquisition sheets, (chromatograms/Re-measurement), [redacted] Multiret Folic 500 mg Tablets, Batch # 70607A, (RT/3 M- Blister), 19 pages.

3i5. Data Acquisition sheets, (chromatograms/Repeat test), [redacted] Multiret Folic 500 mg Tablets, Batch # 70607A1, (CRT/3 M- Blister), 21 pages.

3i6. [redacted] Investigation Addendum, [redacted] Multiret Folic 500 mg Tablets, Batch # 70607A1, OOS Result for Folic Acid, 4 pages.

3i7. Investigation of Deviation Report, Batch # 70607A1, [redacted] Multiret Folic 500 mg Tablets, dated initiated 1/11/08, 1 page.

3i8. Interim Report for Investigation, Investigation [redacted] Multiret Folic 500 mg Tablets, Batch # 70607A1, dated initiated 1/11/08, 2 pages.

3i9. [redacted], Multiret Folic 500 mg Tablets, Batch # 70065A1, (CRT/12-M/Blister), 3 pages.

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3i10. Laboratory Worksheet, [redacted], Multiret Folic 500 mg Tablets, Batch # 70065A1, dated 2/25/08, 13 pages.

3i11. Data Acquisition sheet (chromatograms-original), [redacted] Multiret Folic 500 mg Tablets, Batch # 70065A1, 16 pages.

3i12. Data Acquisition sheet (chromatograms/Remeasurement), [redacted] Multiret Folic 500 mg Tablets, Batch # 70065A1, 19 pages

3i13. Data Acquisition sheet (chromatograms/Repeat), [redacted] Multiret Folic 500 mg Tablets, Batch # 70065A1, 18 pages.

3i14. Investigation memo, fo[redacted], Multiret Folic 500 mg Tablets, Batch # 70607A, dated 2/16/08, 1 page.

3i15. [redacted]vestigation Addendum, [redacted] Multiret Folic 500 mg Tablets, Batch # 70065A1, 3 pages.

3i16. Investigation of Deviation Report, Multiret Folic 500 mg Tablets, Batch # 70065A1, date initiated 1/11/08, 4 pages.

3i17. Laboratory Test Report for Multiret Folic 500 mg Tablets, dated 7/22/98, 1 page.

3i18. A listing noting "Batches Within Expiration Date", Multiret Folic 500 mg Tablets, 1 page.

3j1. Investigation [redacted] Multivita-bets, Batch 70602A1, approved 3/22/08, 9 pages.

3j2. [redacted] Multivita-bets, Batch 70602A1, completed 11/26/07, 6 pages.

3j3. Data Acquisition Using [redacted] Multivita-bets, Batch 70602A1, Assay, checked 11/26/07, 13 pages.

3j4. Data Acquisition Using [redacted] Multivita-bets, Batch 70602A1, Assay for water-soluble, Rep. Test, checked 11/27/07, 10 pages.

3j5. Data Acquisition Using [redacted] Multivita-bets, Batch 70602A1, Repeat Test [redacted] checked 11/28/07, 16 pages.

3j6. Planned Deviation Approval Form, Deviatio[redacted] Approved 1/17/08, 10 pages.

3j7. Thiamine Formulation Overages, 2 pages.

3j8. Annual Data Review, Multi Vita-Bets with 0.5mg Fluoride Tablets, 4/1/06–3/31/07, 1 page.

3j9. Annual Data Review, Multi Vita-Bets with 1.0 mg Fluoride Tablets, 4/1/06 – 3/31/07, 1 page.

3j10. Annual Data Review, Multi Vita-Bets with 0.25 mg Fluoride Tablets, 4/1/06 – 3/31/07, 1 page

3j11. Stability record, Multi Vita-Bets with 0.25 mg Fluoride Tablets, Lot 60226AQ, 4/7/06 – 4/8/07, 1 page.

3j12. Stability record, Multi Vita-Bets with 0.5 mg Fluoride Tablets, Lot 60259AQ, 4/7/06 – 4/8/07, 1 page.

3j13. Stability record, Multi Vita-Bets with 1.0 mg Fluoride, Lot 60205A1, 3/27/06 – 4/2/07, 2 pages.

3j14. Investigation of Deviation Report, Investigation [redacted] initiated 2/14/08, 5 pages.

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3j15. Interim Report for Investigati[redacted] Multivita-Bets, approved 3/20/08, 1 page.

3j16. Method of Analysis, Multivita-Bets with 1.0 mg Fluoride & Iron Chewable Tabs, Effective 3/17/98, 25 pages.

3j17. Multivita-Bets with 1.0 mg Fluoride Chewable Tablets, 2 pages.

3k1. Investigation [redacted] Addendum, Amidrine Capsules, Batch #5638A1, initiated 10/16/07, 10 pages.

3k2. [redacted] Amidrine Capsules Analysis, Batch 5638A1, completed 10/18/07, 14 pages.

3k3. Data Acquisition Using [redacted] Amidrine Capsules, Batch 5638A1, checked 10/16/07, 23 pages.

3k4. Data Acquisition Using [redacted] Amidrine Capsules, Re-measurement, Batch 5638A1, checked 10/17/07, 40 pages.

3k5. Data Acquisition [redacted] Amidrine Capsules, Repeat test Batch 5638A1, checked 10/19/07, 26 pages.

3k6. Data Acquisition [redacted] Amidrine Capsules, Repeat test I, Batch 5638A1, checked 10/19/07, 42 pages.

3k7. [redacted] Amidrine Capsules Analysis, Batch 5638A1, completed 11/17/07, 16 pages.

3k8. Data Acquisition Using [redacted] Amidrine Capsules, Repeat test, Assay, Batch 5638A1, 10/19/07, 21 pages.

3k9. Data Acquisition Using [redacted] Amidrine Capsules, Repeat test, Assay, Batch 5638A1, 10/19/07, 35 pages.

3k10. Investigation Repo[redacted]midrine Capsules, initiated 12/11/07, 67 pages.

3k11. [redacted], Amidrine Capsules, Batch 5638A1, completed 2/20/08. 8 pages.

3k12. Stability Drug Product – Test Report for Amidrine Capsules, dated 8/18/04, 2 pages.

3k13. "Batches Within Expiration Date" listing for Amidrine Capsules, 1 page.

4a1. Annual Product Review, Digoxin Tablets, 0.125mg, January 1, 2007 – December 31, 2007, 9 pages.

4a2. Investigation [redacted] Digoxin Tablets 0.125mg, Batch/Lot 70147A & 70148A, Approved 2/21/07, 20 pages.

4a3. Investigation [redacted] Digoxin Tablets 0.125mg, Batch/Lot 70207A, Approved 3/26/2007, 13 pages.

4a4. Investigation [redacted] igoxin Tablets 0.125mg, Batch/Lot 70770A, Approved 10/19/2007, 8 pages.

4a5. [redacted] pages 211 – 214, Digoxin Tablets 0.125mg, Batch 70148A, completed 2/22/07, 4 pages.

4a6. [redacted] pages 283 – 286, Digoxin Tablets 0.125mg, Batch 70207A, completed 3/15/07, 4 pages.

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4a7. [redacted] pages 190 – 194, Digoxin Tablets 0.125mg, Batch 70770A, completed 9/30/07, 5 pages.

4a8. Planned Deviation Approval Form [redacted] Digoxin Tablets, 0.125mg, Batch 70148A, dated 3/5/07, 18 pages.

4a9. [redacted] pages 241 – 265, Digoxin Tablets 0.125mg, Batch 70148A, completed 4/20/07, 25 pages.

4a10. Rejected Report, Rejection [redacted] dated 7/23/07, 1 page.

4a11. Digoxin Tablets 0.125mg Batch 70207A compression release, bulk product disposition, labeling release, and finished product release dated 6/7/07, 4 pages.

4a12. Digoxin Tablets 0.125mg Batch 70770A compression release, bulk product disposition, labeling release, and finished product release dated 11/30/07, 4 pages.

4b1. Investigation [redacted] Methenamine Mandelate Tablets Batch 70662, Approved 11/06/07, 11 pages.

4b2. Investigation of Deviation Report [redacted] Methenamine Mandelate Tablets Batch 70662, approved 11/29/07, 4 pages.

4b3. Investigation [redacted] Methenamine Mandelate Tablets Batch 70662A, dated 10/29/07, 17 pages.

4b4. Methenamine Mandelate Tablets [redacted] compression release, bulk product disposition, labeling release, and finished product release, 11/30/07, 4 pages.

4b5. Interim Report for Investigation [redacted] dated 11/21/07, 1 page.

4c1. Actavis Temporarily Discontinued Products List, 1 page.

4c2. In-process blend sampling forms, 42 pages.

4c3. Quality Assurance Investigation Into High Blend Uniformity Failure Rate "Interim Report" [redacted] approved 7/5/2007, 36 pages.

4c4. Process Evaluation Protocol, Lamotrigine Chewable Dispersible Tablets 25mg, 1 page.

4c5. FDA comments in response to Minor Amendment regarding ANDA 78-655, Lamotrigine Chewable Dispersible Tablets 25mg, 7/3/07, 6 pages.

4c6. Actavis response to FDA Minor Amendment regarding ANDA 78-655, Lamotrigine Chewable Dispersible Tablets 25mg, 3 pages.

4c7. FDA comments in response to ANDA 40-762, Phendimetrazine Tartrate Tablets 35mg amendments, dated 1/28/2008, 6 pages.

4c8. FDA comments in response to ANDA 40-751, 40-752, 40-753 amendments, dated 2/28/08, 5 pages.

4c9. FDA comments in response to ANDA 78-302, Buspirone Hydrochloride, dated 12/17/2007, 3 pages.

4c10. Actavis FDA Telephone Record, Blend Uniformity Specification, dated 6/14/2007, 1 page.

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4c11. In-Process Testing Report Form, Drixoral Cold and Allergy ER Tablets, Approved 7/26/2007, 1 page.

4d1. Investigation [redacted], Oxycodone HCl Tablets, 15mg, Batch 70164A, Approved 3/8/07, 12 pages.

4d2. Planned Deviation Approval Form, Planned deviation No. [redacted] approved 3/9/07, 12 pages.

4d3. Bulk Disposition Form, Packaging, Finished Product, Labeling Release and Inventory at UPS for Oxycodone HCl Tablets, 15mg, Batch 70164A, Released 4/6/07, 5 pages.

5a1. Analytical Transfer Assessment Between the Quality Control Laboratories at Actavis Little Falls and Actavis Totowa, approved 8/29/07, 9 pages.

5a2. Protocol for Analytical Transfer Between QC Laboratories at Actavis Little Falls and Actavis Totowa, approved 10/22/07, 5 pages.

5a3. Report for Analytical Transfer Between QC Laboratories at Actavis Little Falls and Actavis Totowa, approved 11/16/07, 4 pages.

5a4. Report for Analytical Transfer Between QC Laboratories at Actavis Little Falls and Actavis Totowa, approved 12/20/07, 6 pages.

5b1. Stability Drug Product – Test Report and Specification, Oxycodone HCl Tablets 5mg, approved 2/10/04, 4 pages.

5c1. Investigation [redacted] Betaxolol Tablets 10mg, Batch 60215A1, initiated 3/20/08, 3 pages.

5c2. [redacted], Betaxolol Tablets 10mg, Batch 60215A1, completed 3/21/08, 16 pages.

5c3. Data Acquisition Using Empower 2, Betaxolol Tablets 10mg, Batch 60215A1, checked 3/20/08, 33 pages.

5c4. Data Acquisition Using Empower 2, Betaxolol Tablets 10mg, Batch 60215A1, re-measurement, checked 3/20/08, 40 pages.

5c5. Data Acquisition Using Empower 2, Betaxolol Tablets 10mg, Batch 60215A1, checked 3/22/08, 34 pages.

5c6. OOS/STR Investigation [redacted] Addendum, Betaxolol Tablets 10mg, Batch 60215A1, 3 pages.

5c7. Investigation of Deviation Report [redacted] prepared 3/26/08, 1 page.

5c8. Betaxolol Tablets 10mg & 20mg, Assay and Limit Test, 8/23/2007, 7 pages.

5c9. Betaxolol Tablets 10mg & 20mg, Method Operating Instructions, Approved 10/5/07, 27 pages.

5c10. Betaxolol Tablets 10mg & 20mg, Related Substances, Method Comparison, 2/14/08, 7 pages.

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5c11. Letter sent to [redacted] for ANDA 75-541, Betaxolol Tablets 10mg & 20mg, 4/21/08, 44 pages.
5c12. Betaxolol 20mg Batches within Expiration Date, 2 pages.
5c13. Stability Summary for Betaxolol Tablets 10mg Batch 60215A1, dated 4/18/08, 6 pages.

5d1. Currently Manufactured Vitamin Product List and Finished and Stability Tests, 60 pages.

5e1. Investigation [redacted] Amantadine HCl Capsules, Assay, Approved 1/30/07, 11 pages.
5e2. Investigation [redacted] Amantadine HCl Capsules, Assay, Approved 7/16/07, 13 pages.
5e3. Investigation [redacted] Amantadine HCl Capsules, Assay, 3 pages.
5e4. Investigation Addendum, [redacted] Amantadine HCl Capsules, Assay, 3 pages.
5e5. Justification for Extension Investigation [redacted] dated 2/28/2008, 1 page.
5e6. Method Remediation List, 2 pages

6b1. Investigation 01-102, Oxycodone Hydrochloride Tablets, USP 5mg, Lot 70976A, approved 1/18/08, 10 pages.
6b2. Investigation [redacted] Oxycodone Hydrochloride Tablets, USP 30mg, Lots 80095A1, 80096A, 80165A1, approved 3/11/08, 21 pages.
6b3. Finished Product Release forms for Oxycodone HCL Tablets, USP 30mg, Filling Code 80095A1 & 80096A1 and Oxycodone HCL Tablets, USP 15mg, Filling Code 80165A1, dated 3/1108 and 3/12/08, 3 pages.
6b4. Production Summary for Investigation [redacted] page.
6b5. Investigation [redacted] Oxycodone Hydrochloride Tablets, USP 30mg, Lot 80174A, approved 3/26/08, 16 pages.
6b6. Equipment Usage and Cleaning Logs used in manufacture of Oxycodone Hydrochloride Tablets, Batches 80321A and 803009A, 16 pages.

7. Field Alert Report, 2 pages.

8ei1. Change Control Request Form, [redacted] approved 10/31/2007, 11 pages.
8ei2. Stability Protocol, Buspirone HCl Tablets USP, 5mg and 10mg, 2 pages.
8ei3. Stability Study Design/Request Form, Buspirone HCl Tablets USP, 5mg, Tracking No. 06-361, 4 pages.
8ei4. Stability Request Form, [redacted] 1 page.
8eii1. Change Control Request Form, [redacted] approved 11/15/2007, 9 pages.
8eii2. Stability Study Protocol – Revision 5/5/06, Drixoral Tablets, Formula B, issued 5/2/07, 4 pages.

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8f1. Investigation [redacted] Oxycodone Hydrochloride Tablets, USP 5mg, Lot 70761A1, approved 1/29/08, 57 pages.

8f2. Investigations from September 2007 to Present by Product, 9 pages.

9a1. [redacted], Effective 11/3/06, 8 pages.

9a2. [redacted], Investigation of Deviations, Revision 9, 16 pages.

9b1. Departmental Operating Instructions [redacted] Investigation of Out of Specification Test Results, Revision 12, Effective 7/2/07, 18 pages.

9b2. [redacted] Laboratory Investigations, Revision 14, 15 pages.

9c1. [redacted], Revision 02, Effective 10/31/07, 4 pages.

10ai1. [redacted] dated 12/27/07, 1 page.

10ai2. Process Validation Report for Digoxin Tablets, page 5 of 59, 1 page.

10ai3. Equipment Usage and Cleaning Logs and PM logs, dated 9/10/07through 4/14/08, 9 pages.

10ai4. Work Order 1039, dated 2/12/08, 1 page.

10aii1. [redacted], dated 3/31/08, 1 page.

10aii2. Equipment Usage and Cleaning Log, 12/05/07 through 4/4/08, 2 pages.

10aiii1. [redacted] dated 4/4/08, 1 page.

10aiii2. Equipment Usage and Cleaning Log, 1/15/08 through 5/6/08, 4 pages.

10b1. [redacted] effective 1/10/08, 7 pages.

10bi1. [redacted] Approved 8/31/07, 15 pages.

10biii1 [redacted] 2/20/08, 9 pages.

11d1. Investigation [redacted] Multivita-Bets with 1.0mg Fluoride Tablets, Batch 60061A1, approved 3/25/08, 18 pages.

12. Commitment Letter to NWJ DO to recall products with OOS stability results, dated 4/9/2008, 10 pages.

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13. Commitment Letter to NWJDO to cease distribution and manufacture of DESI products, dated 4/22/2008, 3 pages.
14. Copy Commitment Letter to NWJDO to assess and remediate deficiencies, dated 4/28/2008, 21 pages.
15. Letter to NWJDO regarding third party review and release of certain quarantined lots, dated 5/6/2008, 33 pages.
16. Letter to NWJDO regarding updated commitments, dated 5/20/2008, 2 pages.
17. Letter to NWJDO regarding the Actavis Riverview facility, dated 5/21/2008, pages.
18. Actavis sites, 5 pages.
19. Facility layout/diagram (Riverview, NJ facility), 2 pages
20. Floor plan (Little Falls, NJ facility), 1 page
21. Product List, 8 pages.
22. Products with Indication, 6 pages.
23. List of Controlled Substances, 1 page.
24. Organizational Charts, 18 pages.
25. Pending ANDAs and Pending Supplements, 2 pages.
26. Letter to FDA, dated 6/4/07, Extension of the Current Actavis Totowa LLC Facility, 1 page.
27. Digoxin Batches Manufactured at Actavis Totowa-Riverview Site, 1 page.
28. [redacted], 4 pages.
29. Currently Manufactured DESI Product List, 1 page.
30. Discontinued Products, 1 page.
31. DESI Products for Further Regulatory Filing, 1 page.
32. Response to Letter Regarding Unapproved New Drugs Dated August 24, 2007, 44 pages.
33. Compact disc (master CD), Vitamin and DESI Labels and Inserts.
34. [redacted], 9 pages.
35. Departmental Operating Instructions, [redacted] Initiation, Notification, Handling, and Reporting of a Drug Product Recall, 2 pages.
36. Investigation of Deviation Report, Investigation [redacted], 40 pages.
37. Final Report for the Process Validation for Quinapril Hydrochloride and Hydrochlorothiazide Tablets, 20mg/12.5mg, 41 pages.
38. Little Falls Product Release List, 1 page.
39. Remaining Product Within Expiry, 22 pages.
40. [redacted] 7 pages.

ATTACHMENTS

- FDA 482, Notice of Inspection, dated 3/18/08, 1 page.

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Establishment Inspection Report	FEI:	2244683
Actavis Totowa LLC	EI Start:	03/18/2008
Totowa, NJ 07512	EI End:	05/20/2008

- FDA 482, Notice of Inspection, dated 4/3/08, 1page.
- FDA 482, Notice of Inspection, for 101 East Main Street, Little Falls, NJ, dated 4/22/08, 1page.
- FDA 482, Notice of Inspection, dated 5/20/08, 1page.
- FDA 483, Inspectional Observations, dated 5/20/08, 16 pages
- Letter regarding unapproved prescription drugs from FDA, dated 8/23/07, 4 pages.
- List of Field Alerts generated from District filings, 2 pages
- Field Alert for Phentermine HCl Capsules, USP 30mg, dated 4/24/08, 3 pages
- Field Alert for Gyburide (Micronized) Tablets, USP, 1.5mg, dated 11/29/07, 3 pages.
- Field Alert for Pentazocine and Naloxone Hydrochlorides Tablets, USP 50mg/0.5mg, dated 2/4/08, 3 pages.
- Field Alert for Mirtazpine Orally Disintegrating Tablets, 15mg, dated 4/4/08, 3 pages

Erin D. McCaffery, Investigator

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RELEASE

REVIEWED BY C.O. 5/28/09 DATE